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LaNeve et al.

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(54) **METHOD OF FORMING AND DECORTICATING A VOID IN A SACROILIAC JOINT**

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(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 17/063,609, filed on Oct. 5, 2020, now Pat. No. 11,058,556, which is a (Continued)

(51) **Int. Cl.**

A61F 2/46	(2006.01)
A61B 17/16	(2006.01)
A61B 17/02	(2006.01)
A61B 17/84	(2006.01)
A61B 17/92	(2006.01)
A61F 2/30	(2006.01)

(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/4611*** (2013.01); ***A61B 17/025*** (2013.01); ***A61B 17/1671*** (2013.01); ***A61B 17/848*** (2013.01); ***A61B 17/92*** (2013.01); ***A61F 2/30988*** (2013.01); *A61B 17/1604* (2013.01); *A61B 17/90* (2021.08); *A61B 2017/00477* (2013.01); *A61B 2017/0256* (2013.01); *A61B 2017/922* (2013.01); *A61F 2002/4681* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/4611; A61B 17/7055; A61B 17/3421
See application file for complete search history.

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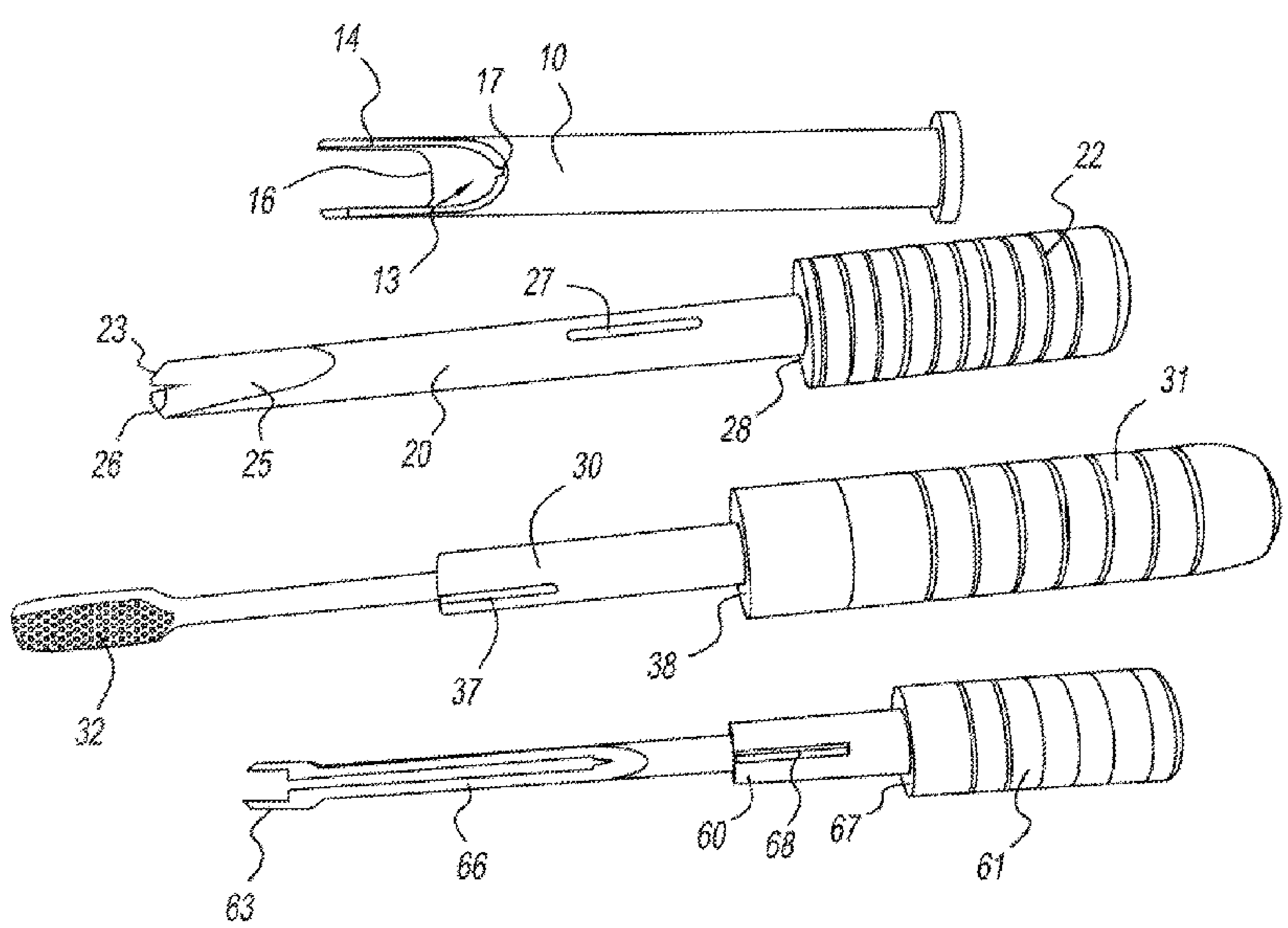
Primary Examiner — Andrew Yang
(74) *Attorney, Agent, or Firm* — Stepben E. Kelly; Thomas J. Banks; Hill Ward Henderson, P.A.

(57) **ABSTRACT**

A method for forming and abrading an implant void in a sacroiliac joint ("SI Joint") without the use of a rotary cutting instrument. The method incorporates a multimodal abrading device having abrading surfaces on opposing sides and an open tip comprising a cutting edge. The method includes the step of using the abrading head to cut bone tissue from the SI Joint at an insertion point while simultaneously using the abrading surfaces to decorticate the cortical bone at the insertion point.

12 Claims, 25 Drawing Sheets



Related U.S. Application Data

continuation-in-part of application No. 16/851,840, filed on Apr. 17, 2020, now Pat. No. 11,154,402.

(60) Provisional application No. 62/910,913, filed on Oct. 4, 2019.

(51) **Int. Cl.**

A61B 17/00	(2006.01)
A61B 17/90	(2006.01)

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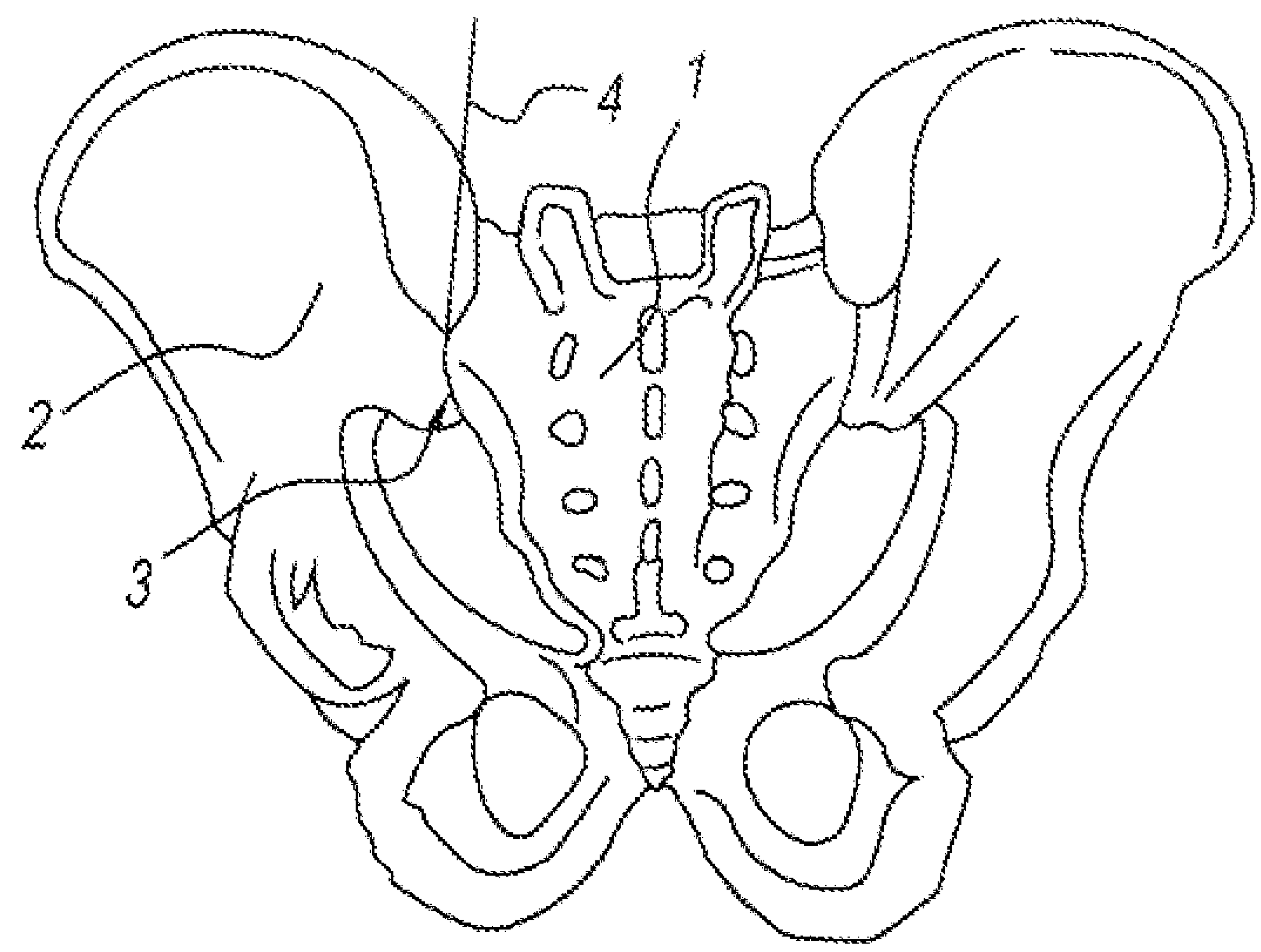


FIG. 1

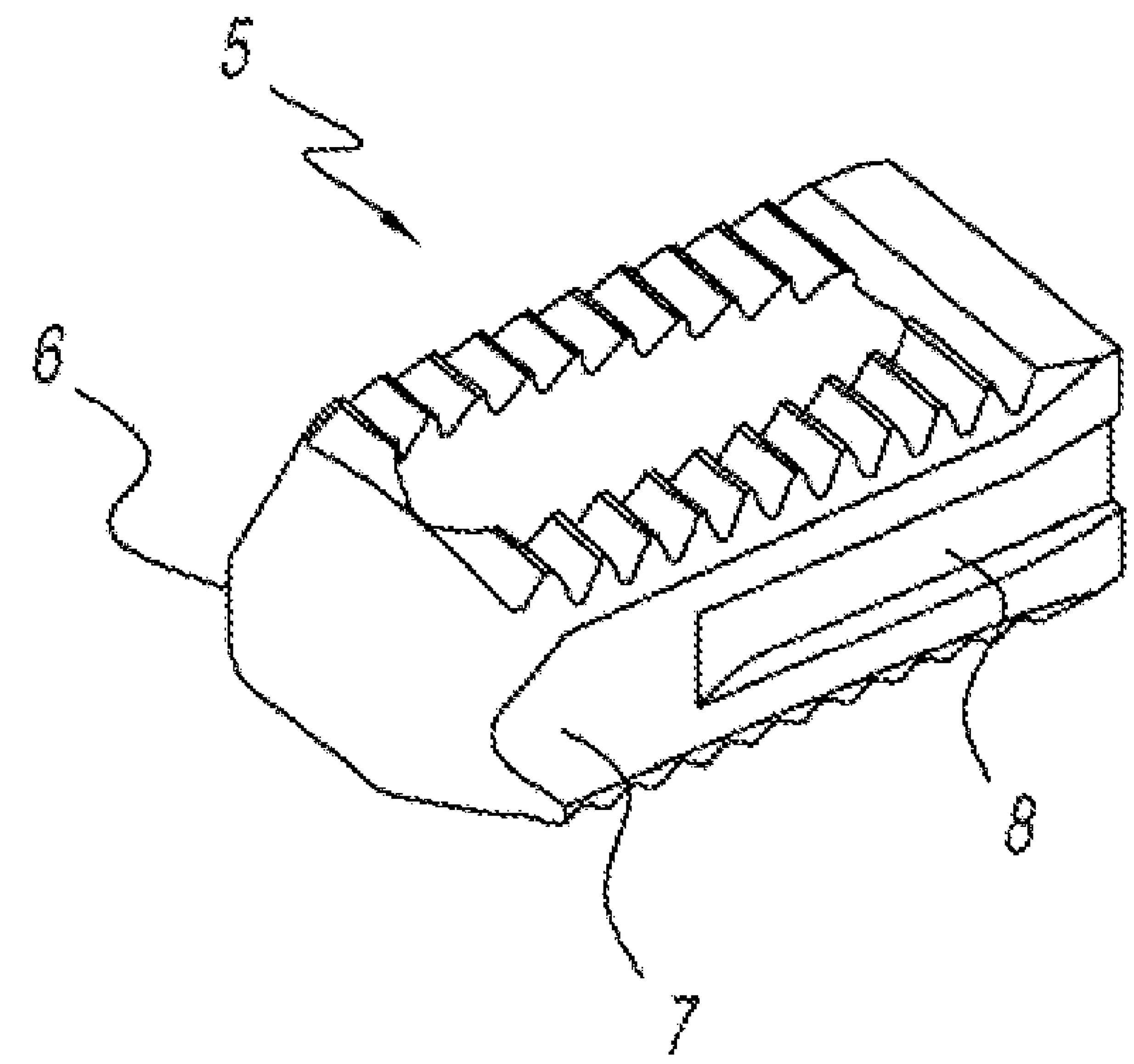


FIG. 2

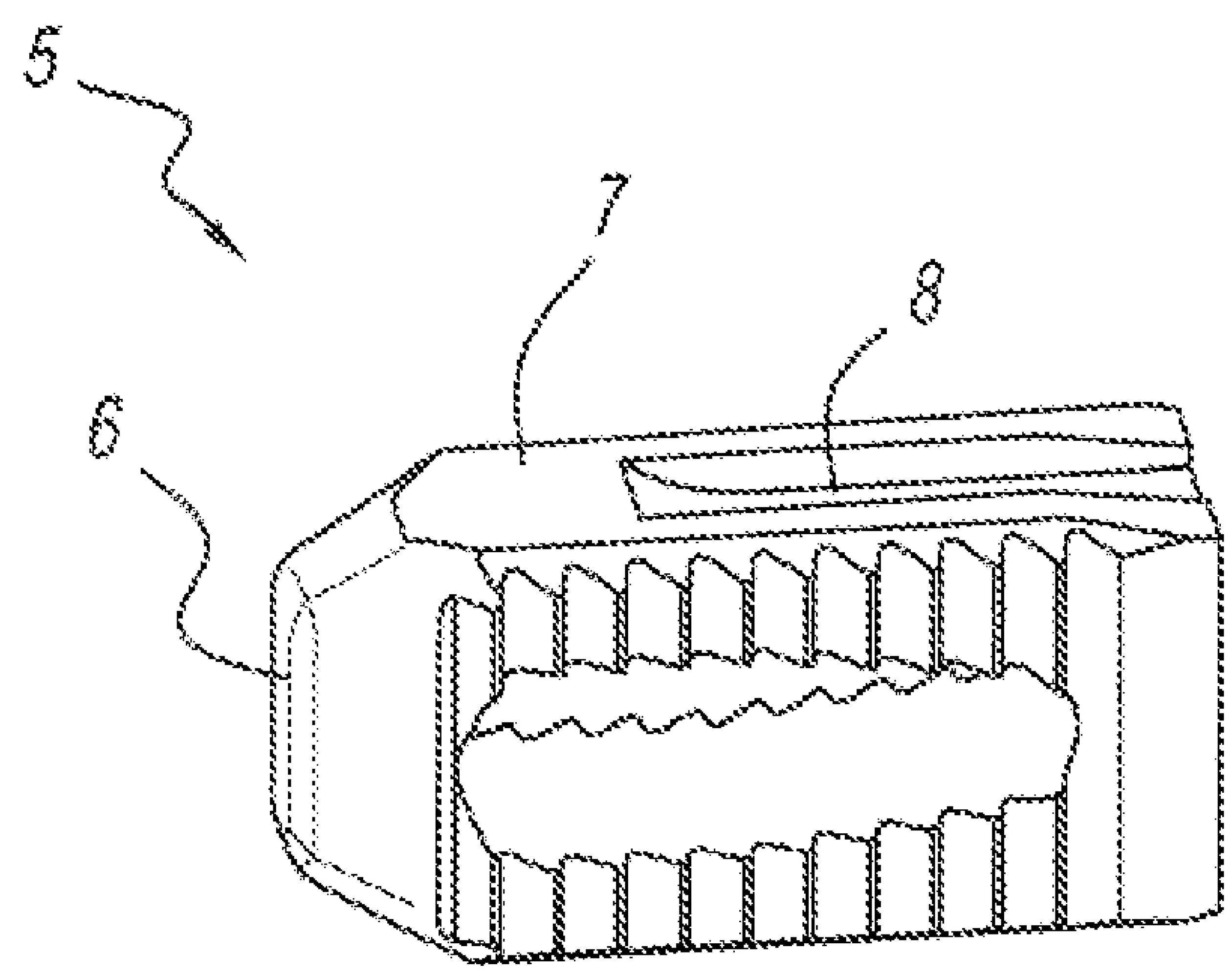


FIG. 3

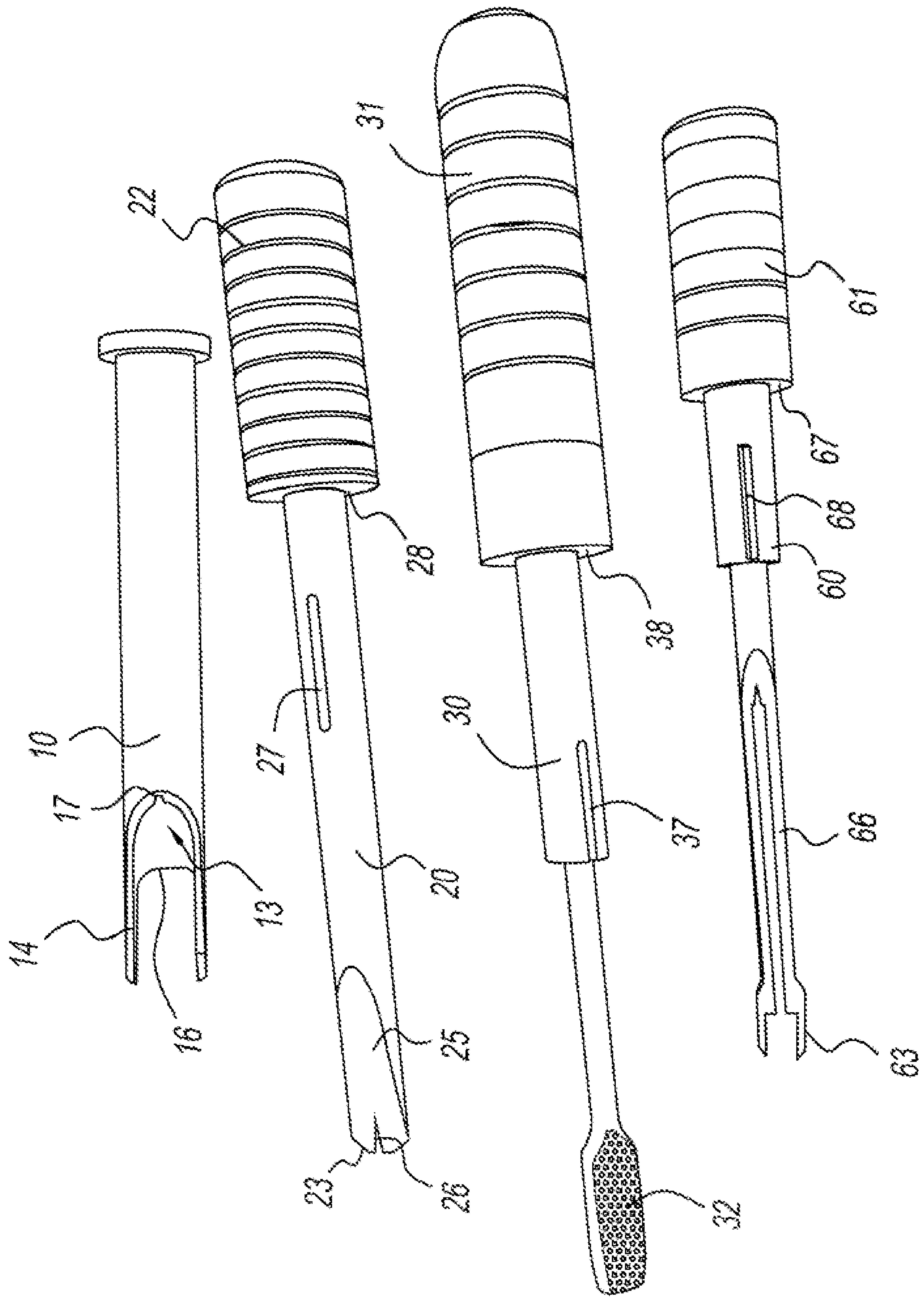


FIG. 4

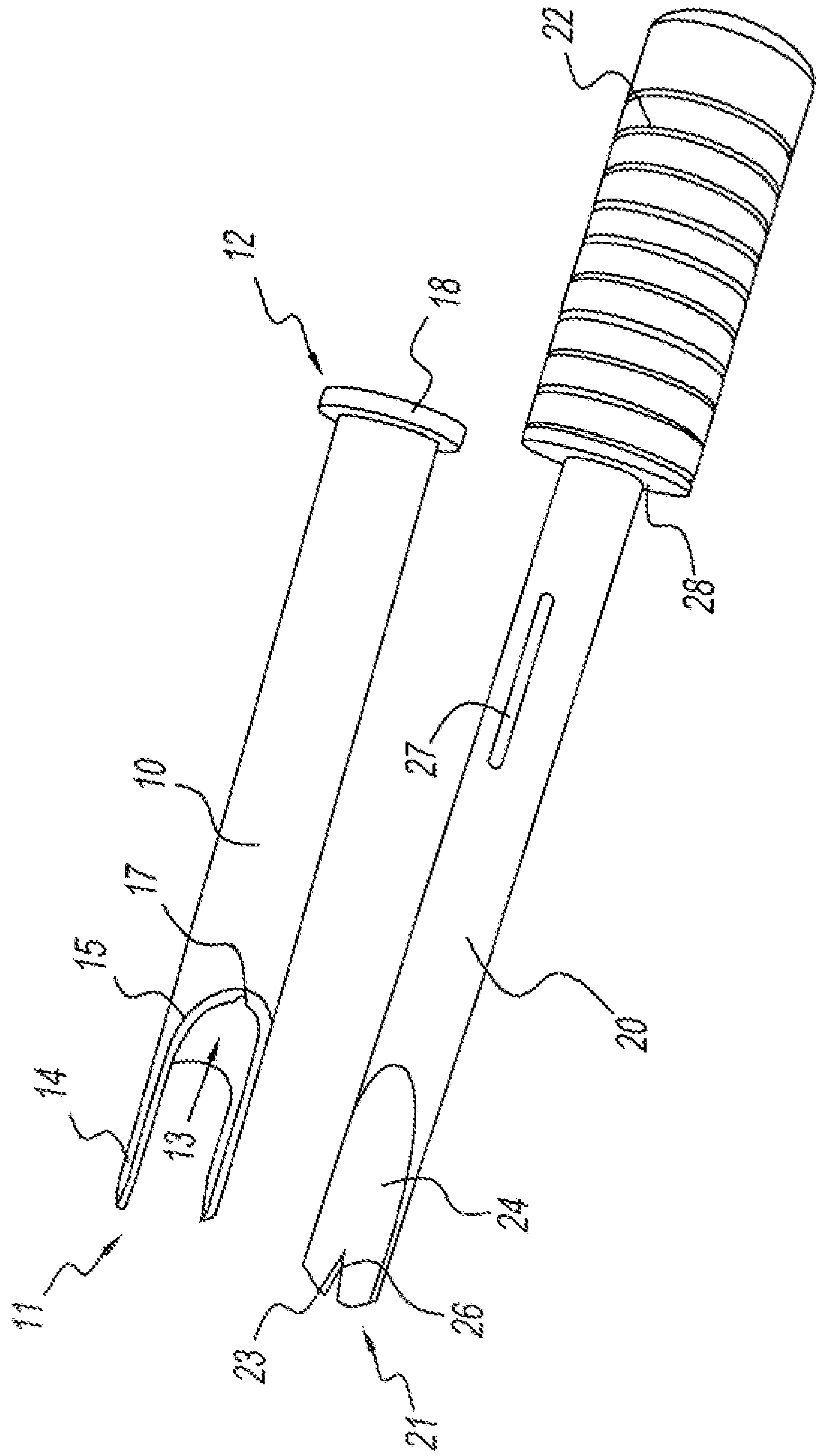


FIG. 5

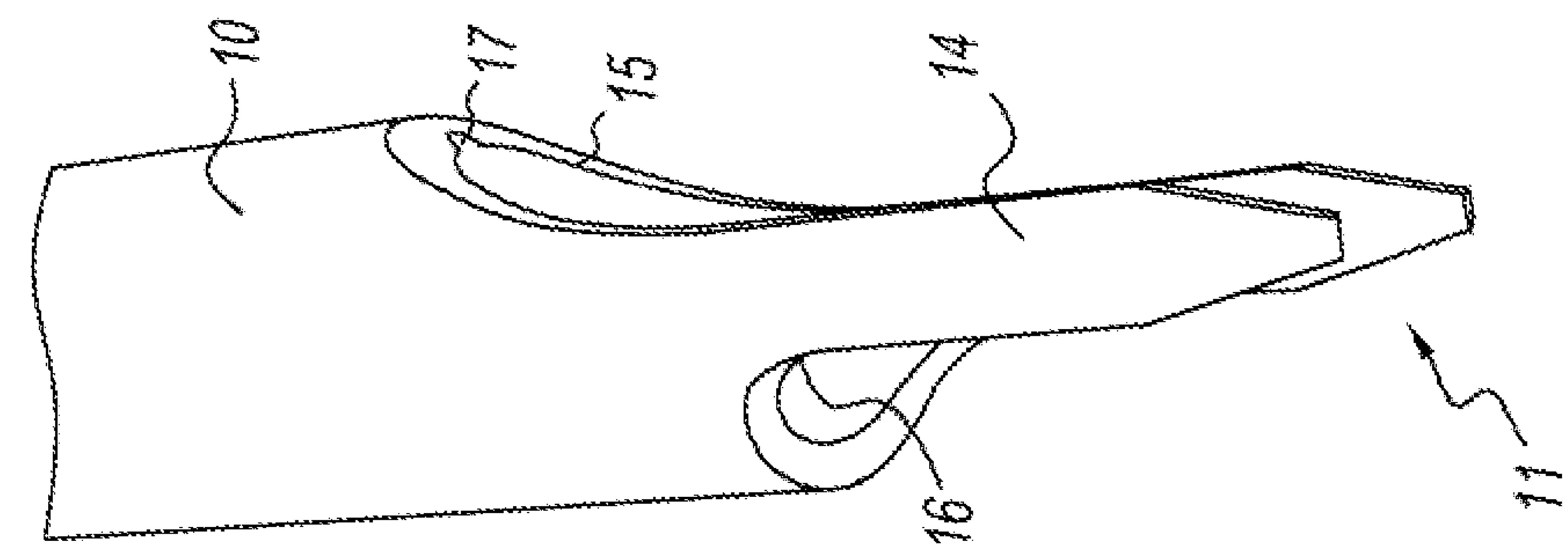


FIG. 7

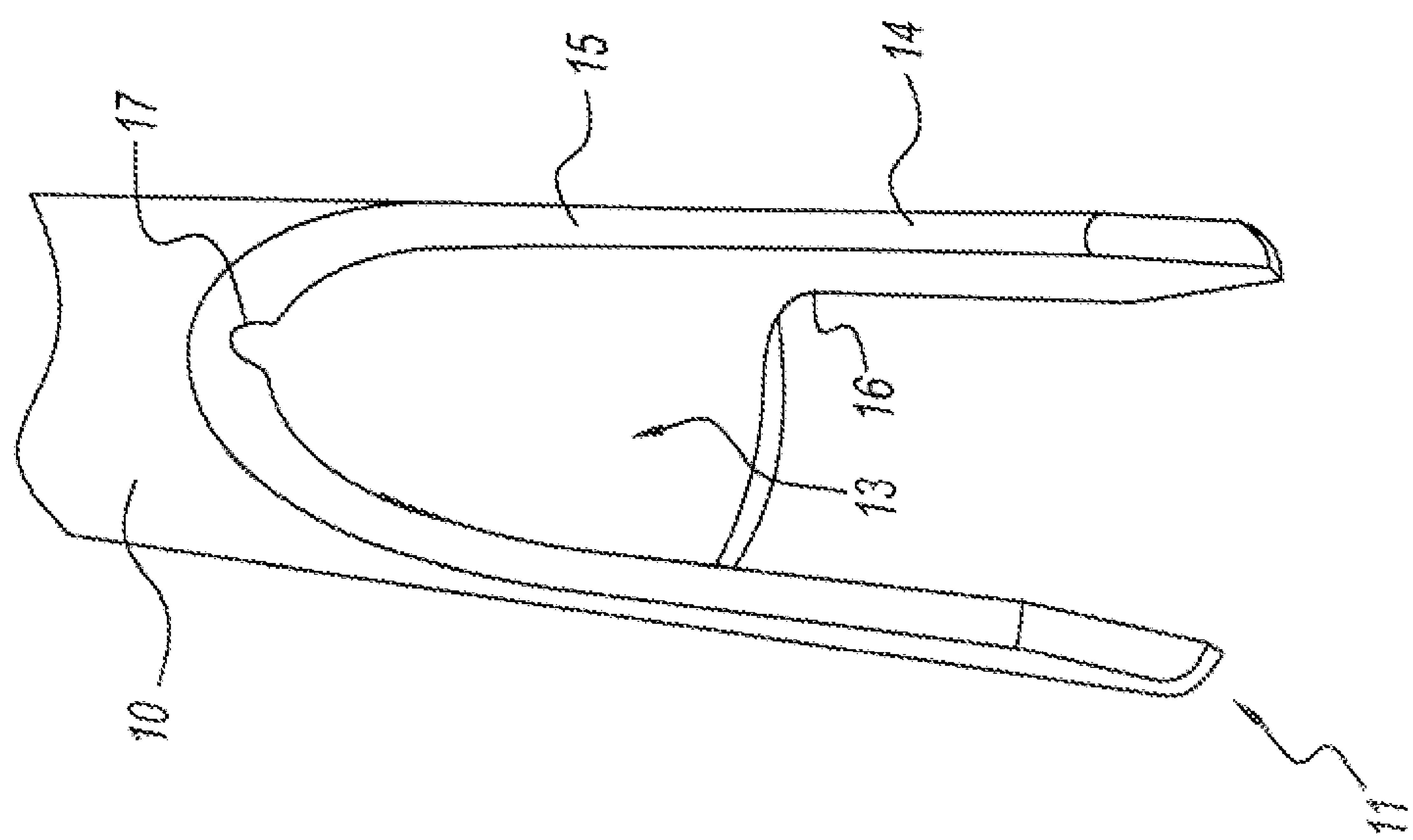


FIG. 6

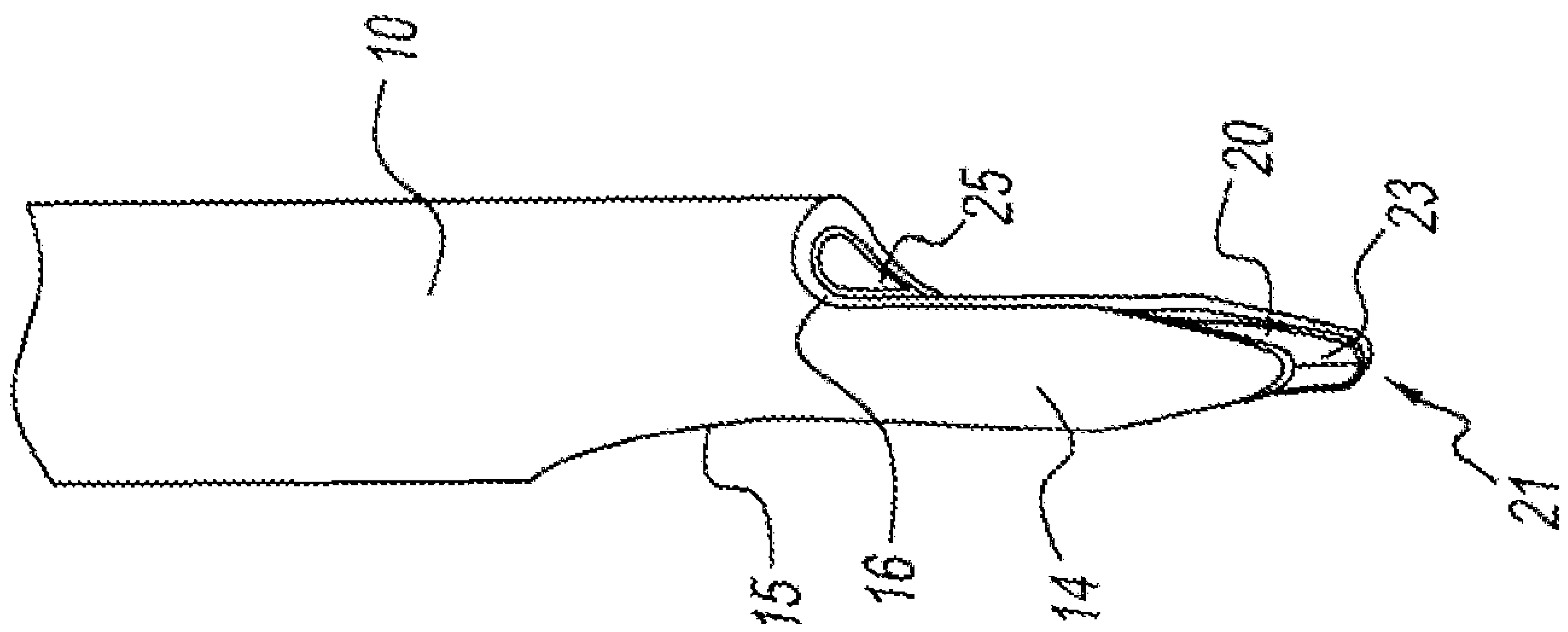
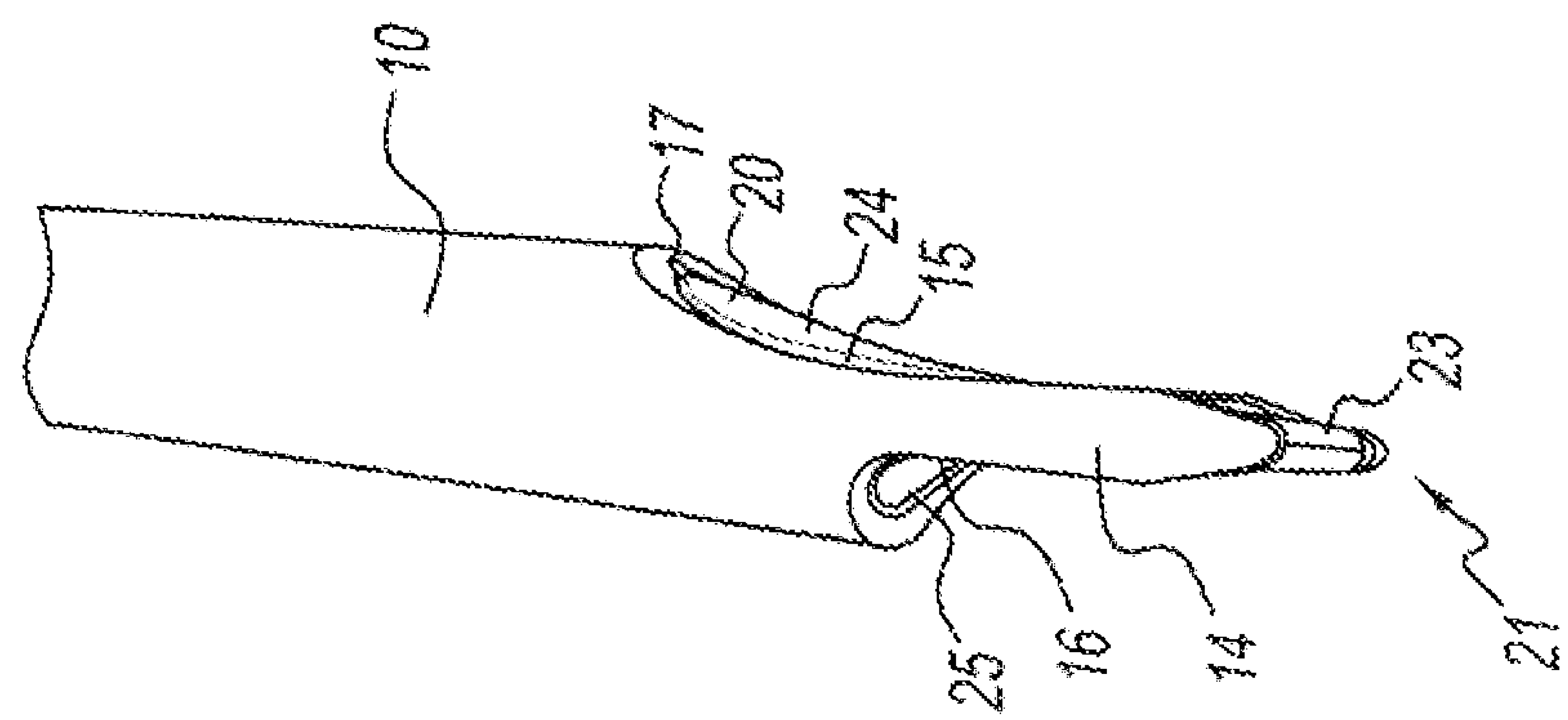


FIG. 9



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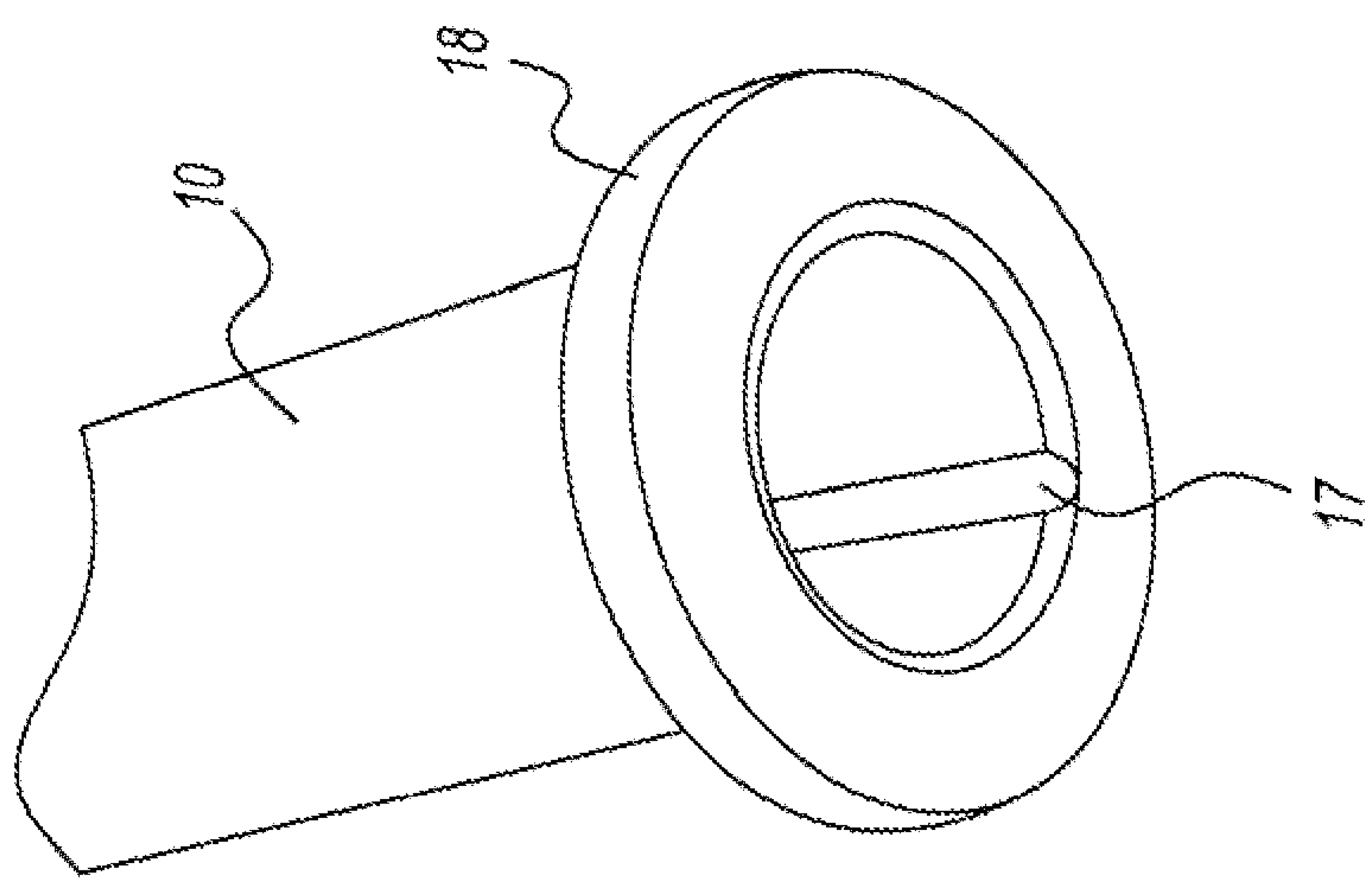
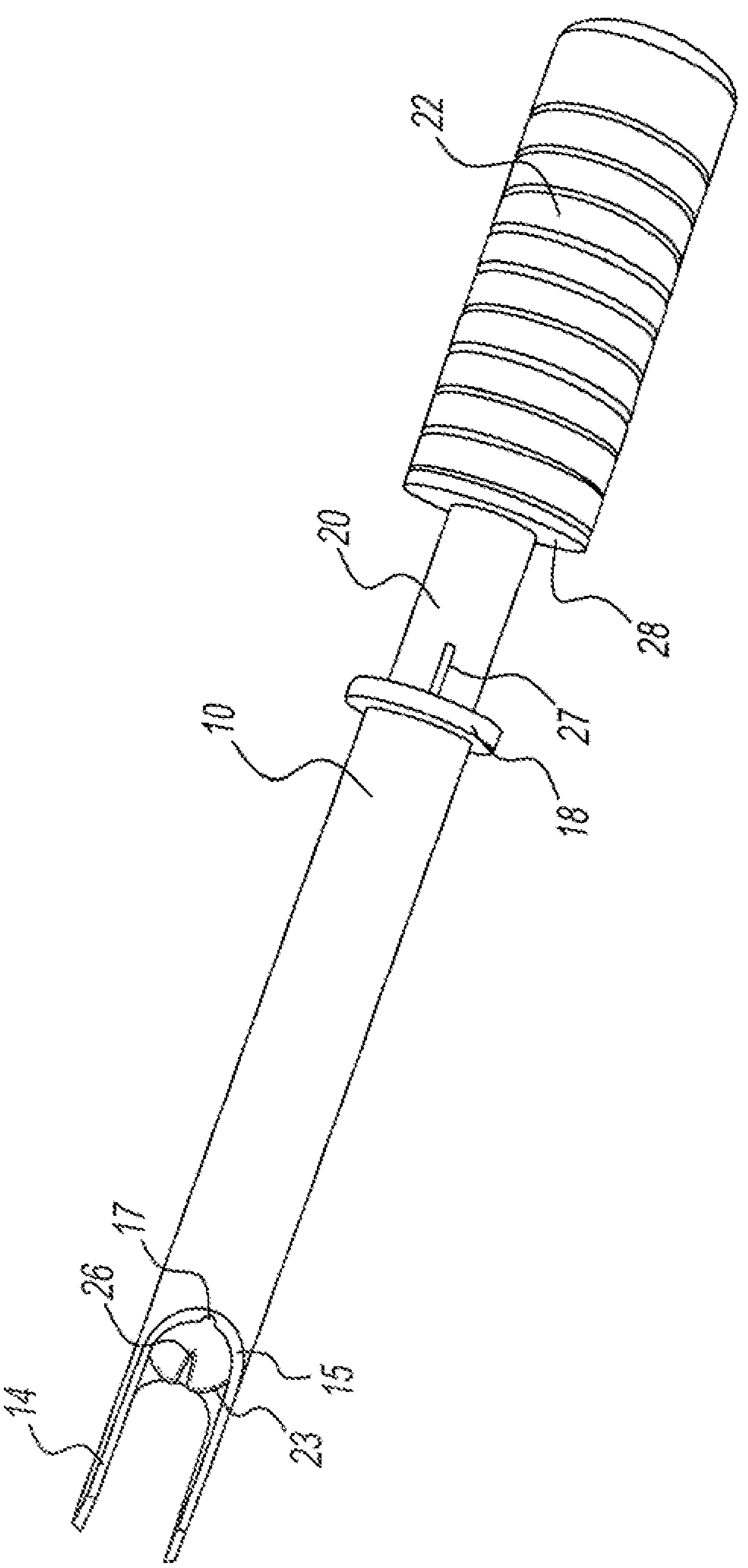


FIG. 10



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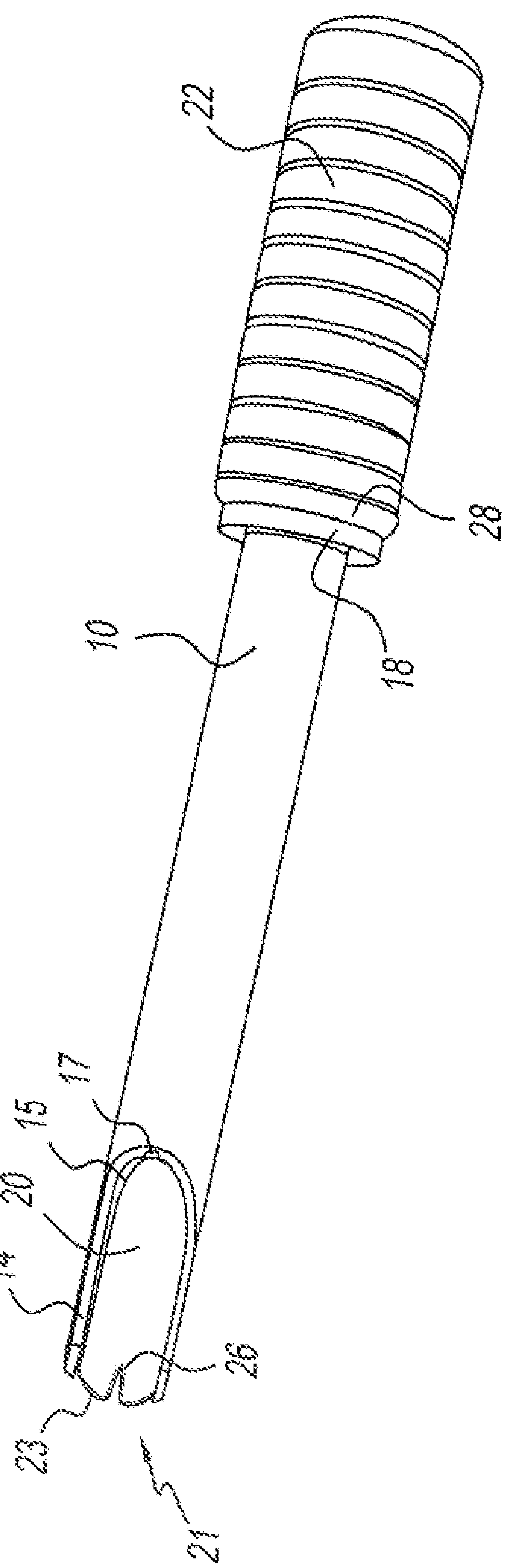

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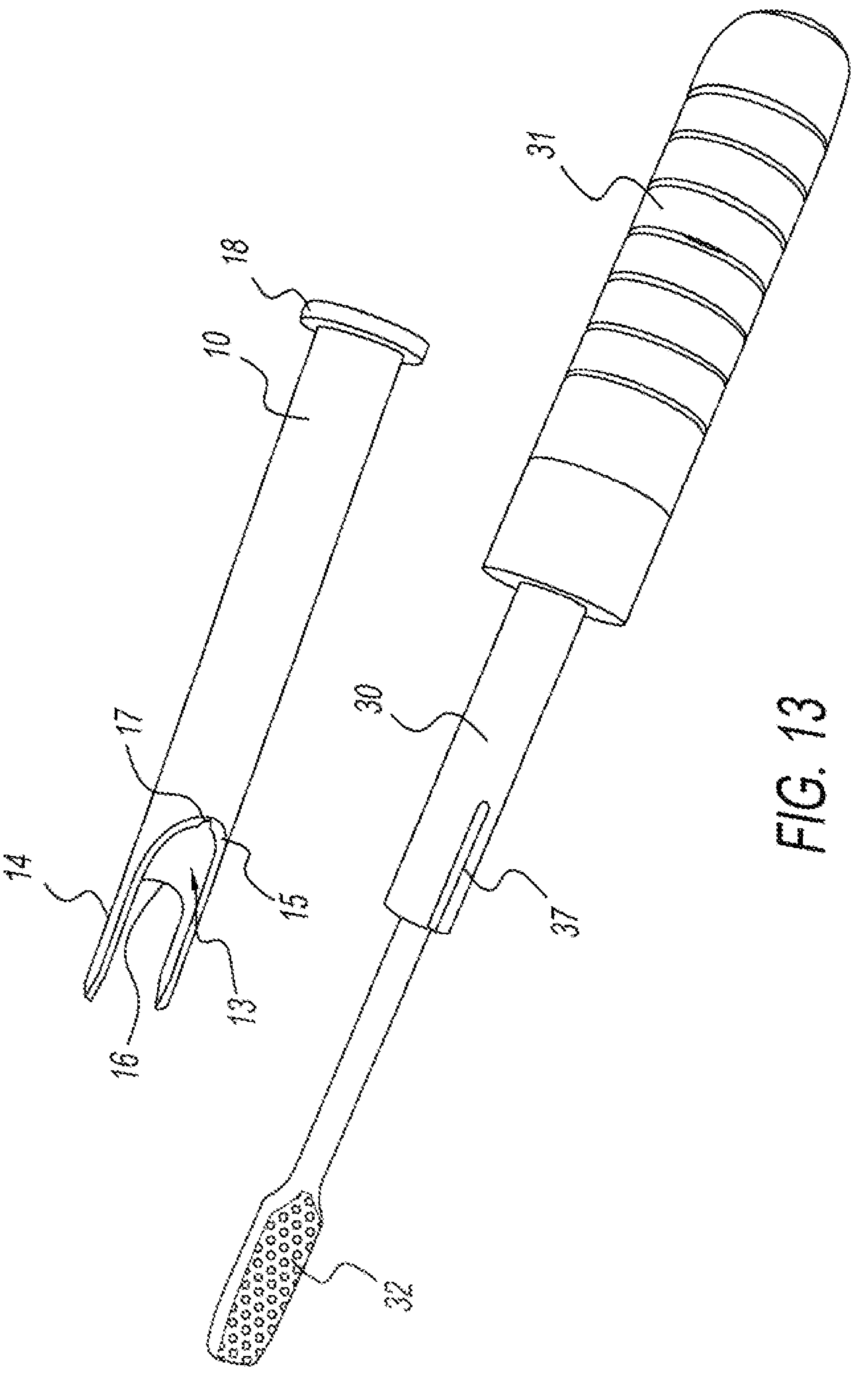

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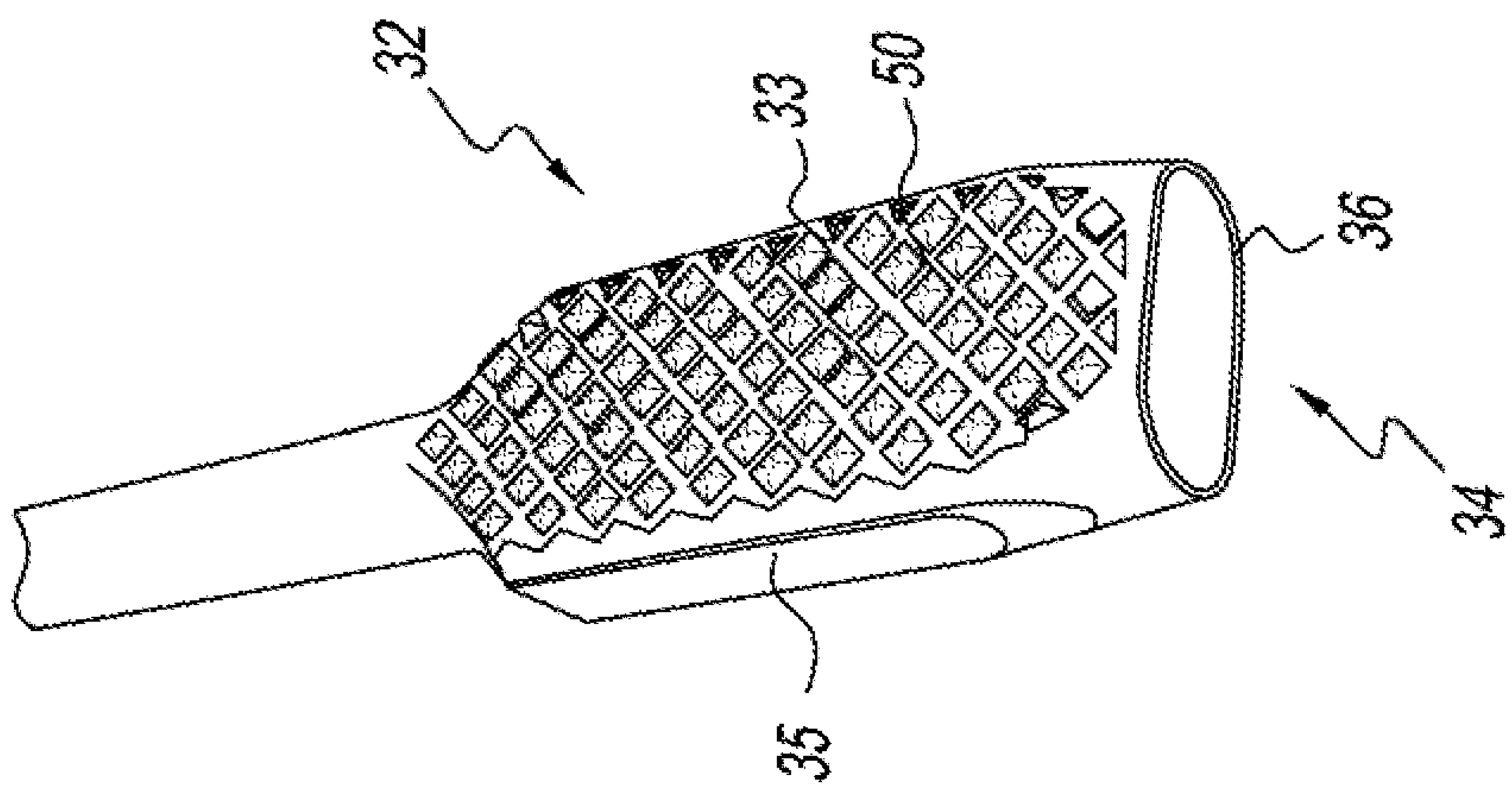

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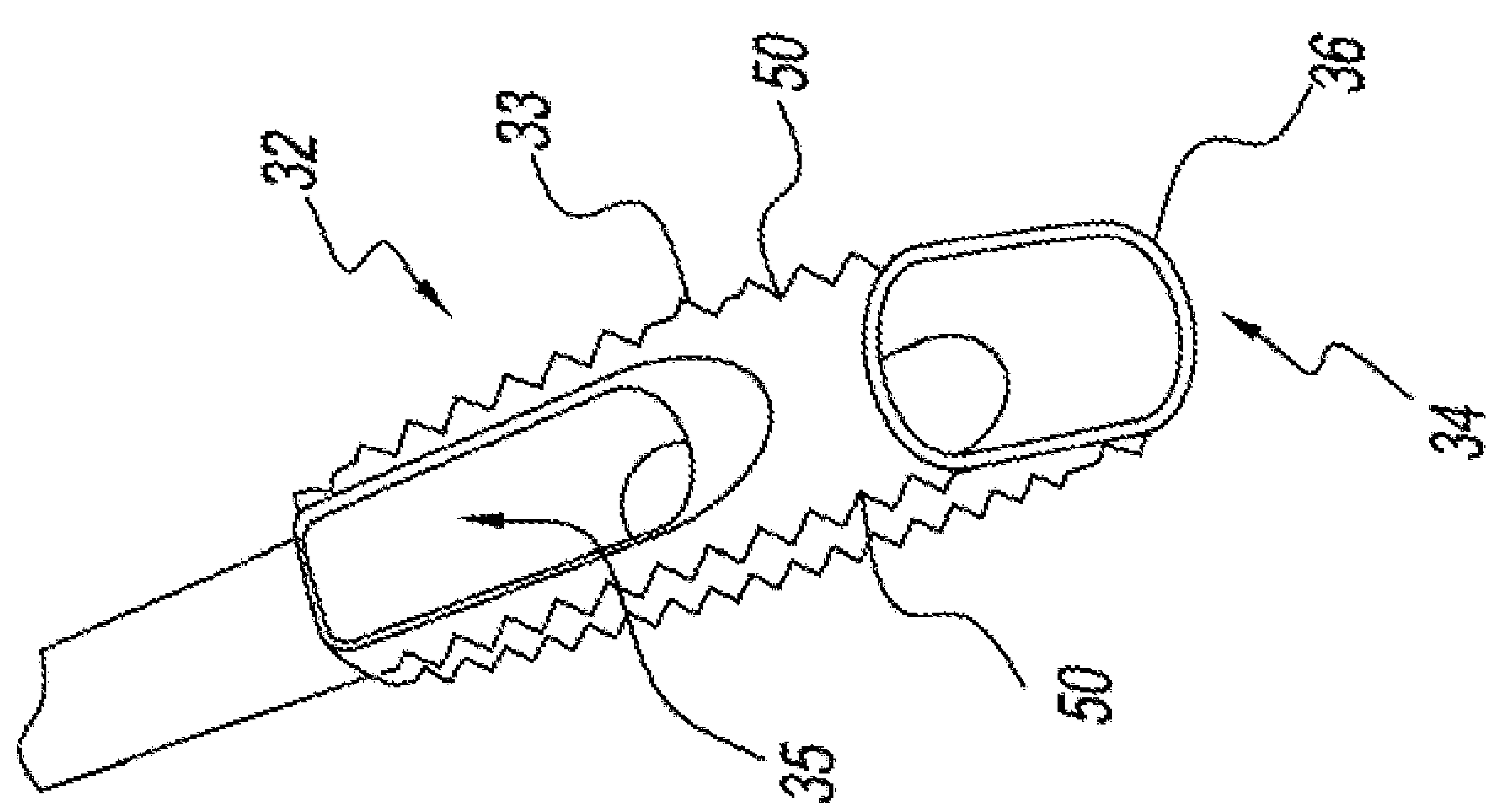

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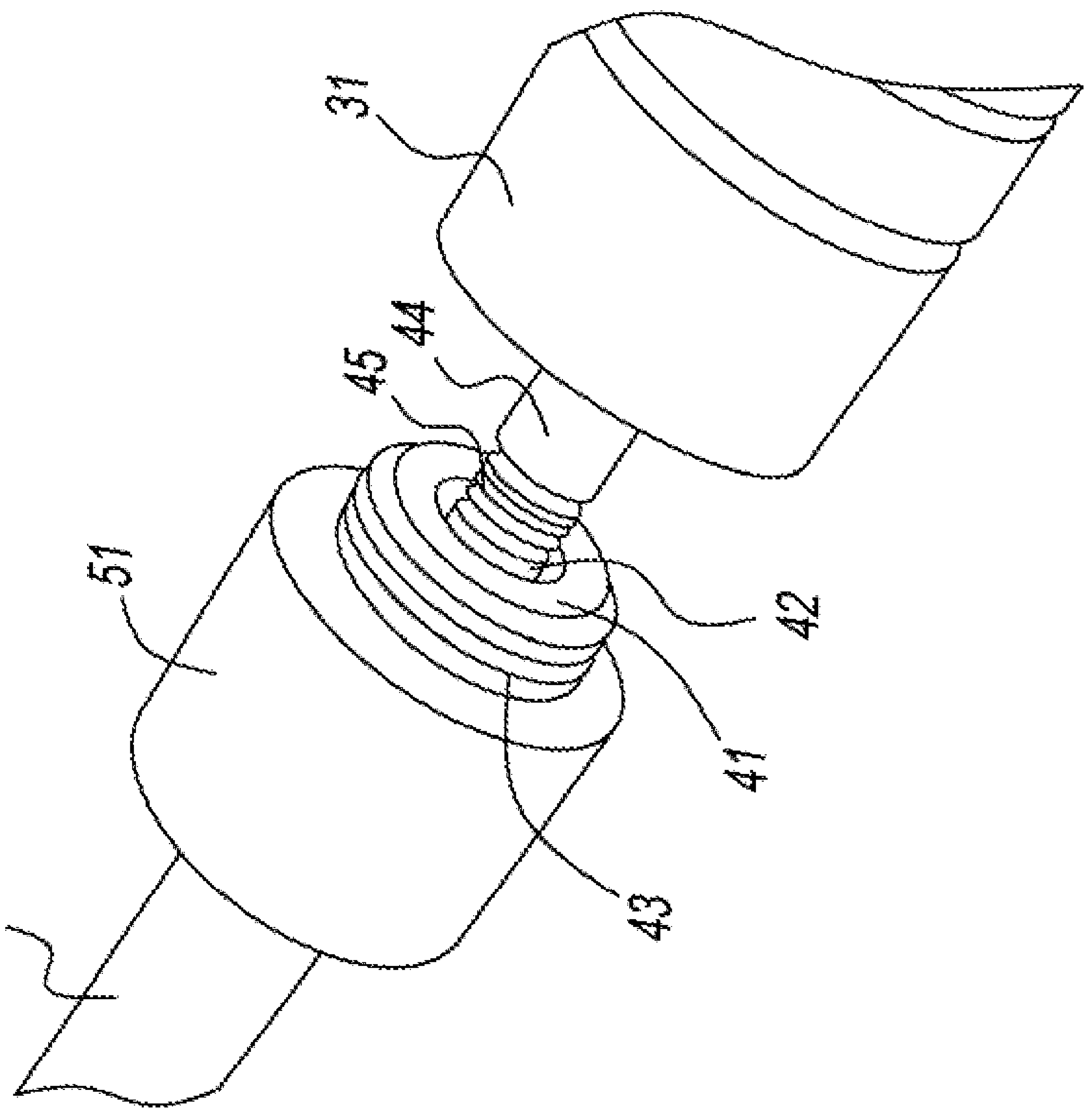

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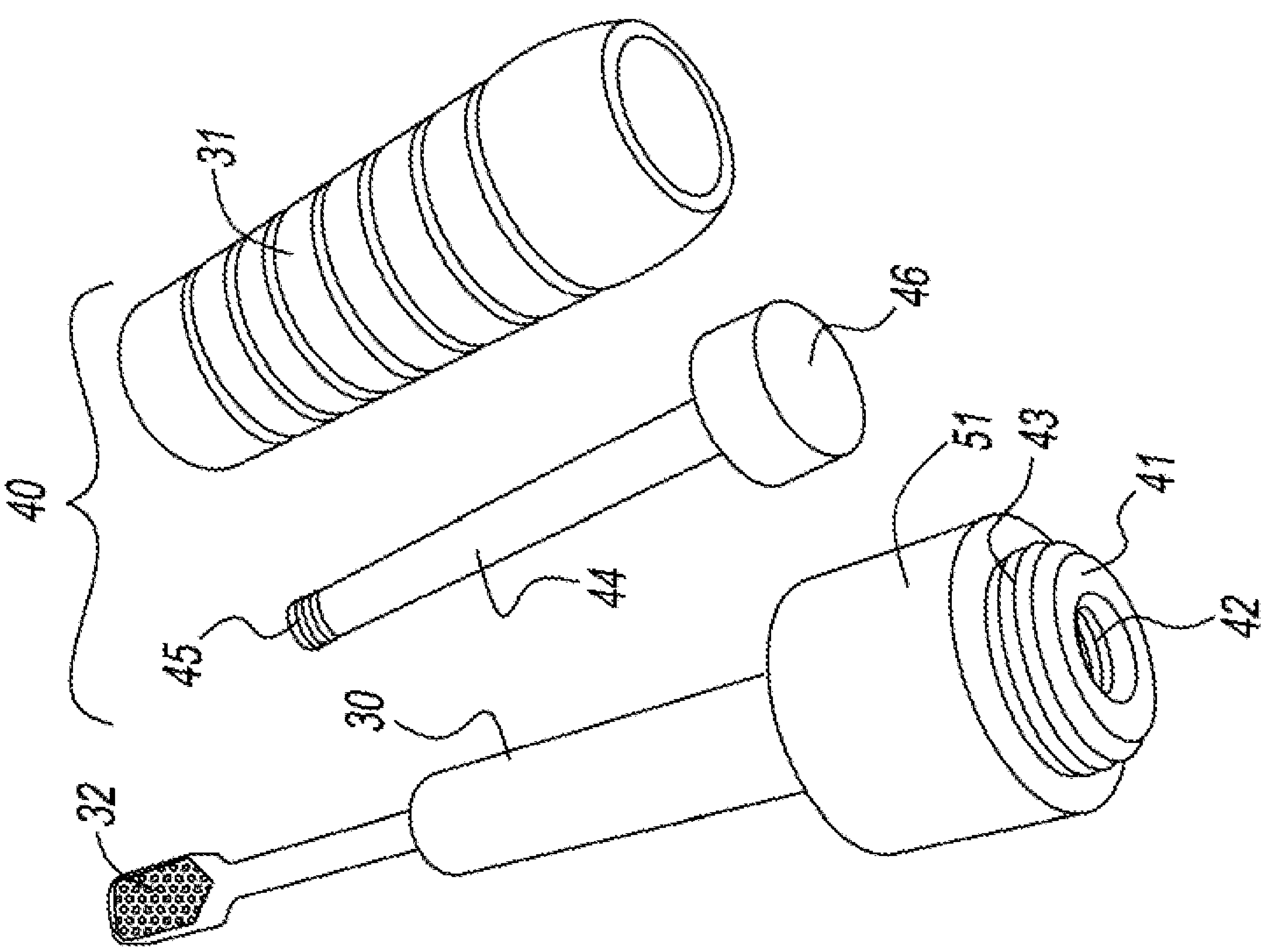

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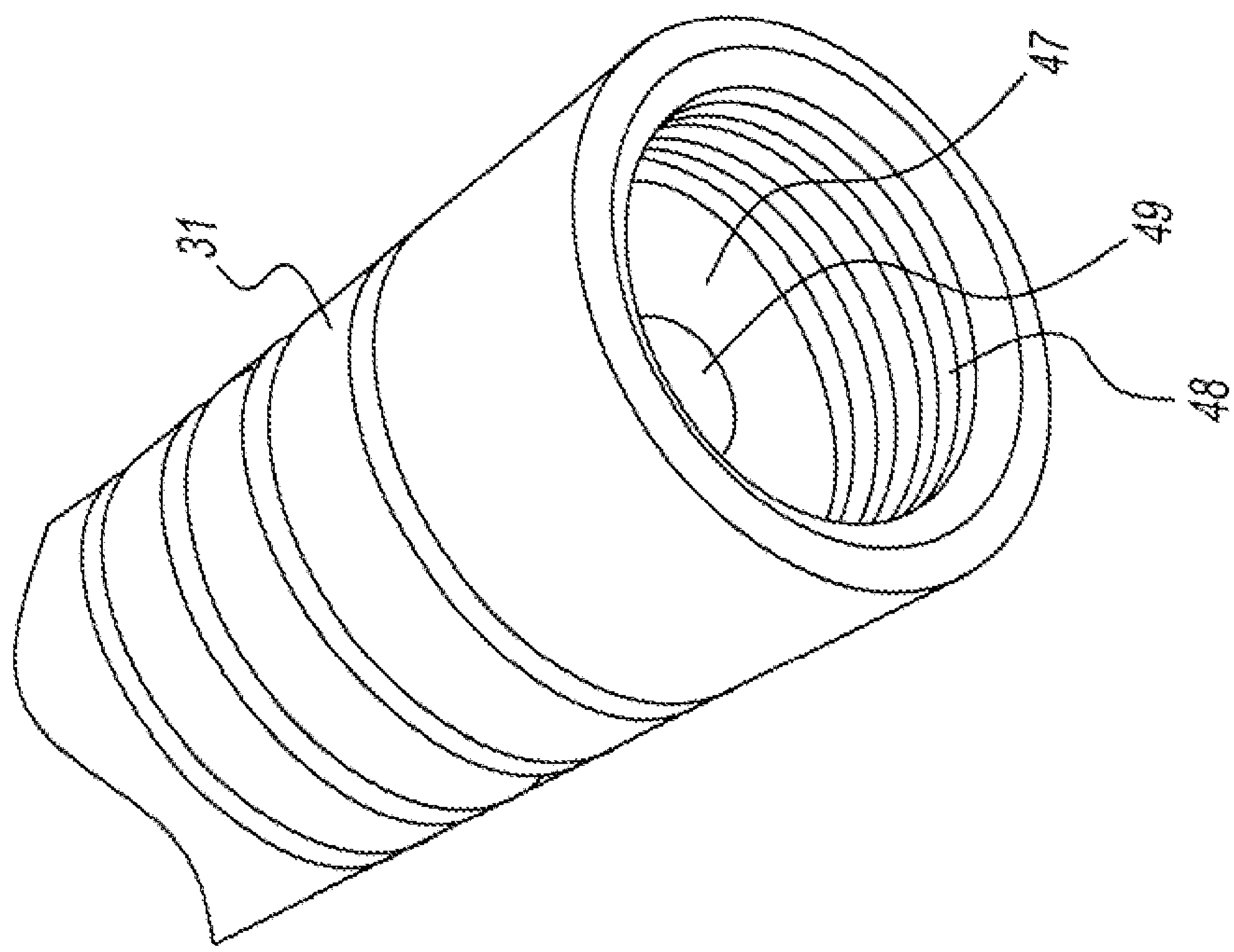

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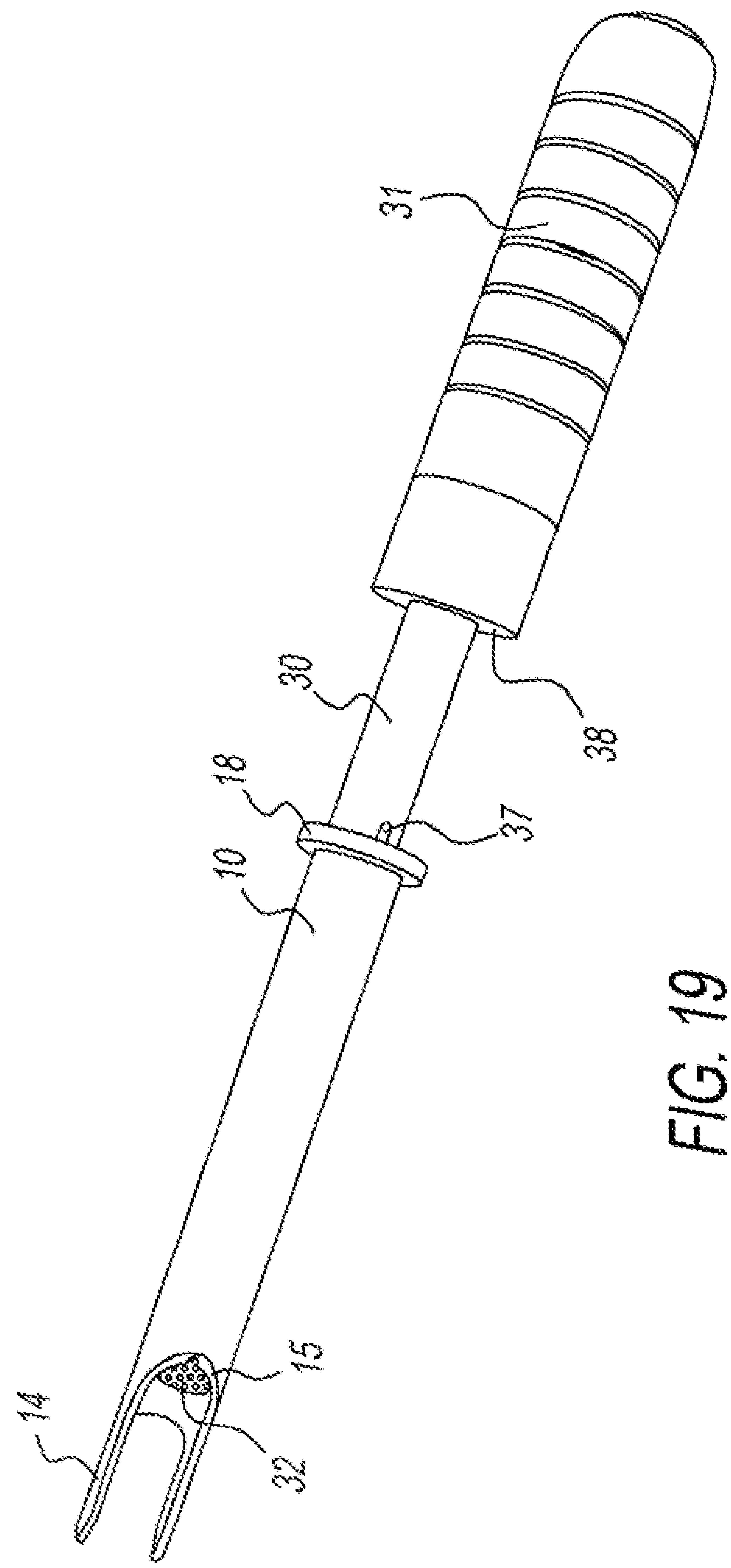

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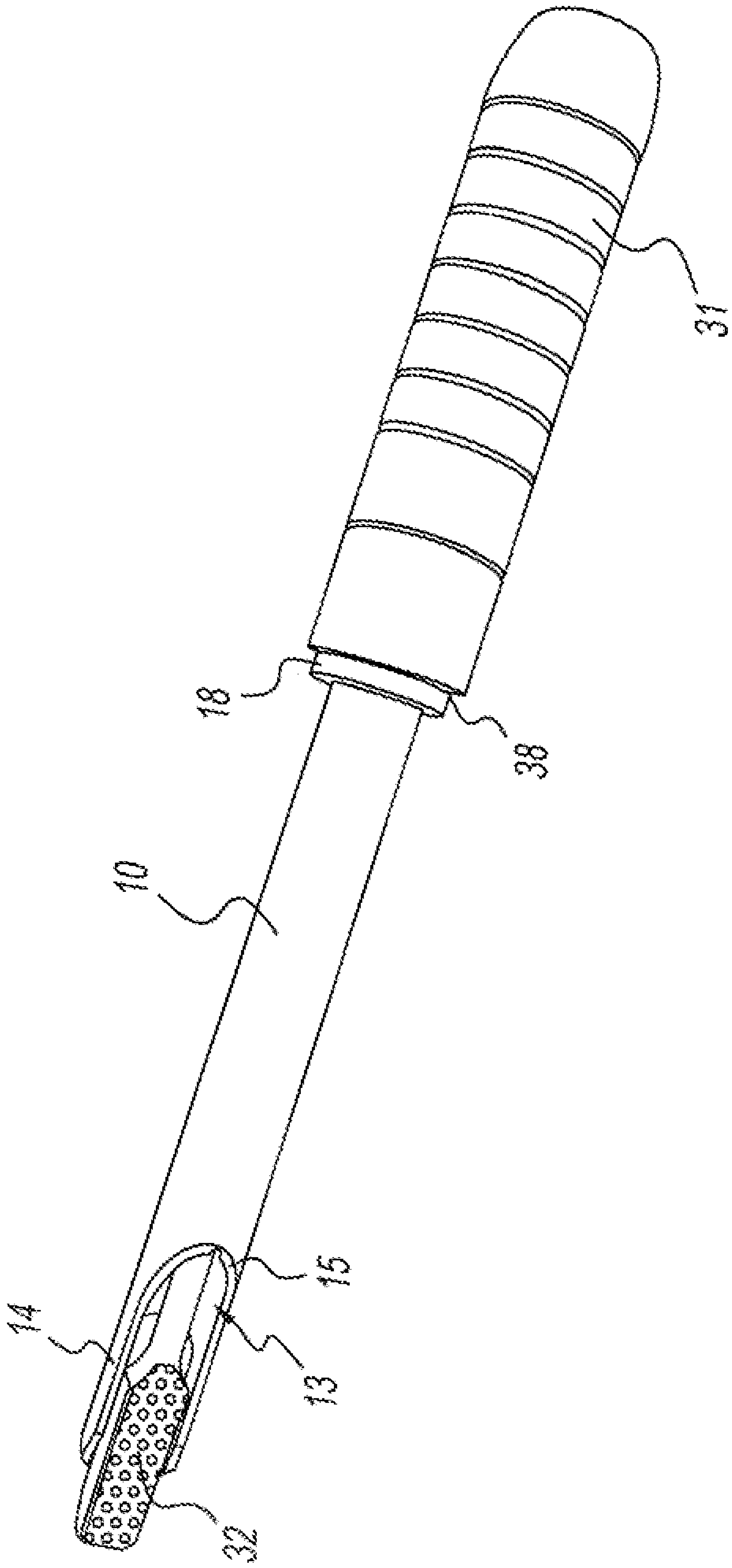

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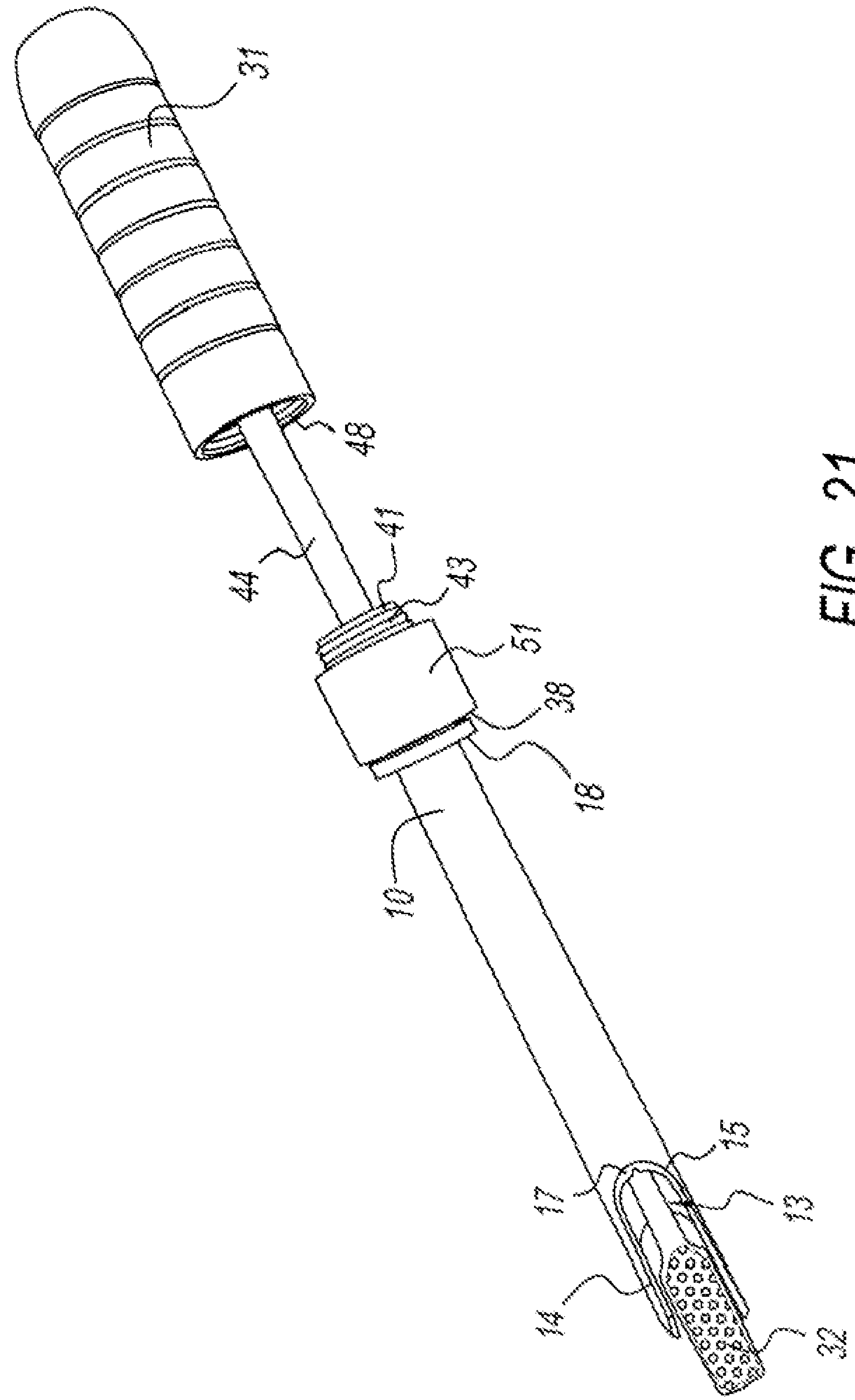


FIG. 21

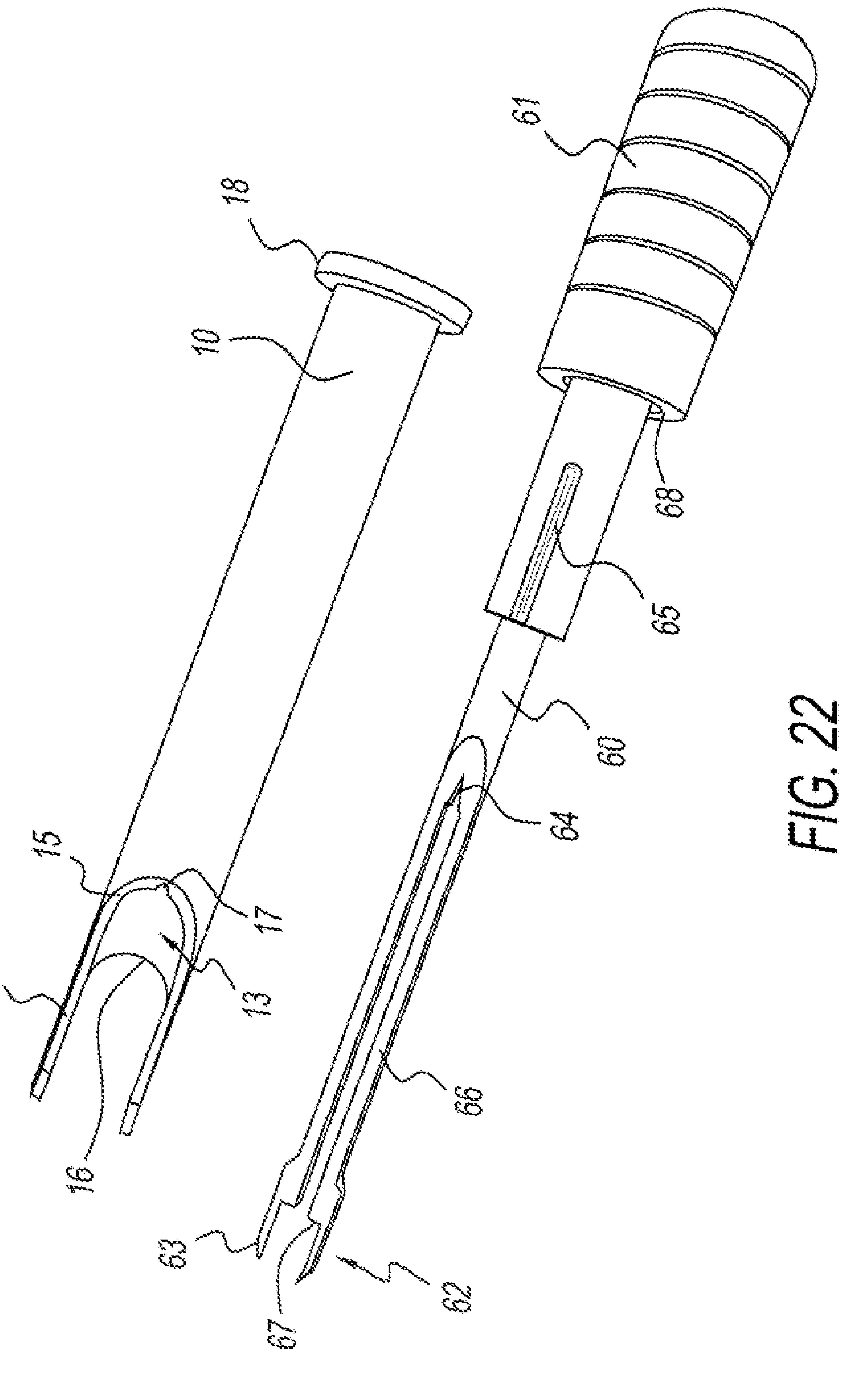


FIG. 22

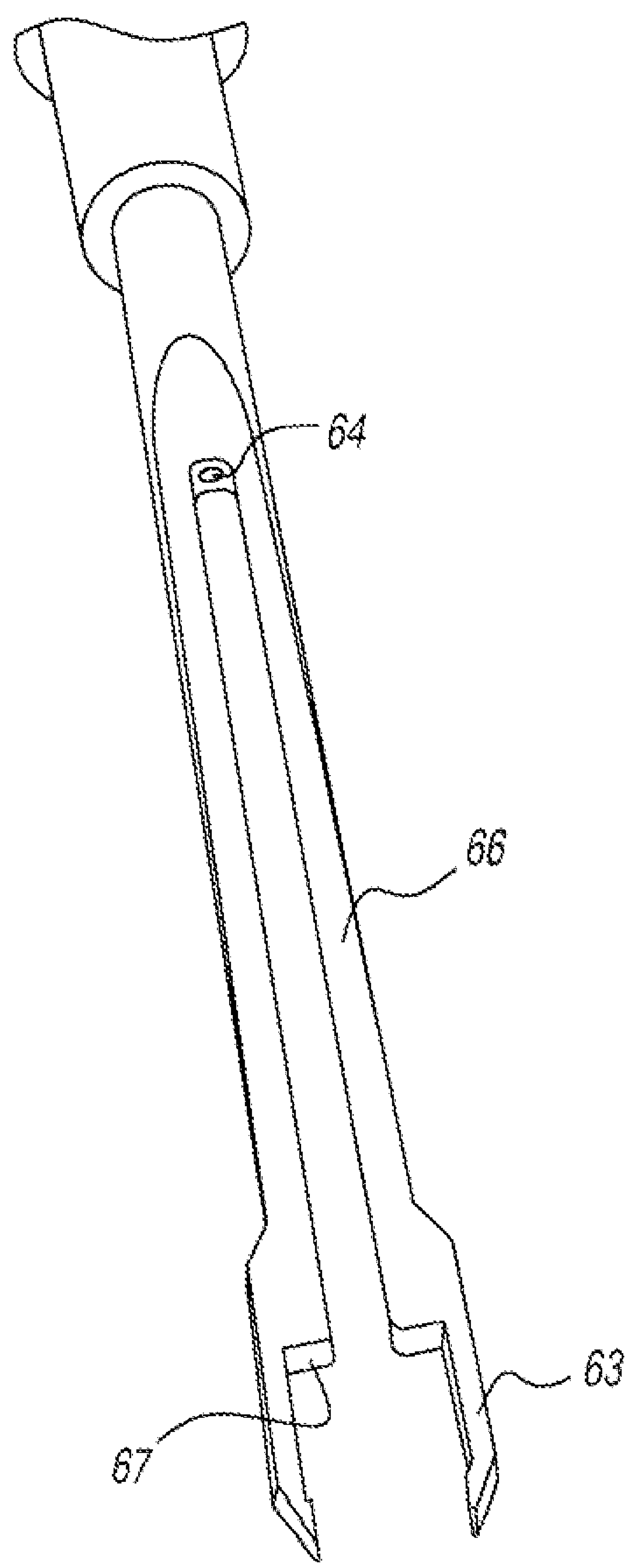
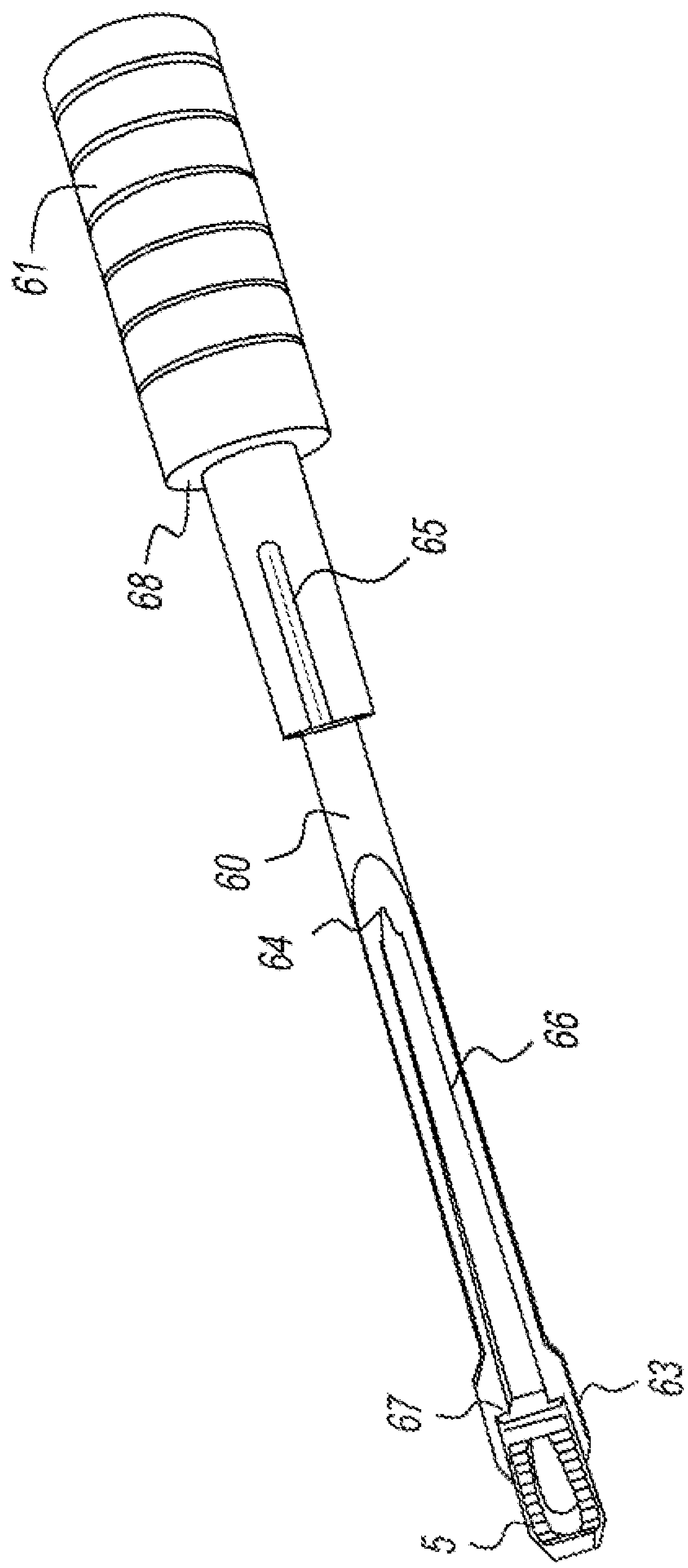


FIG. 23



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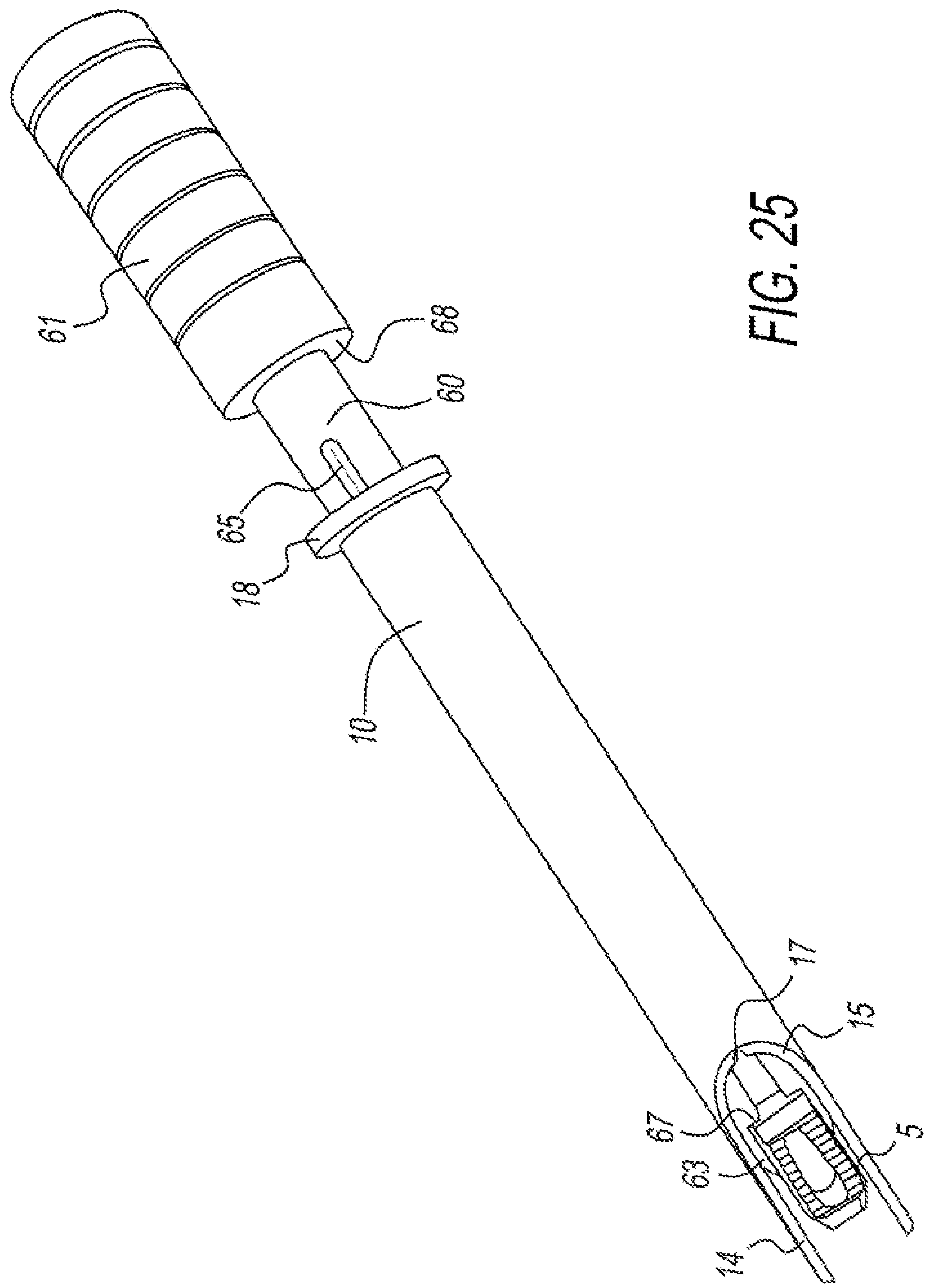

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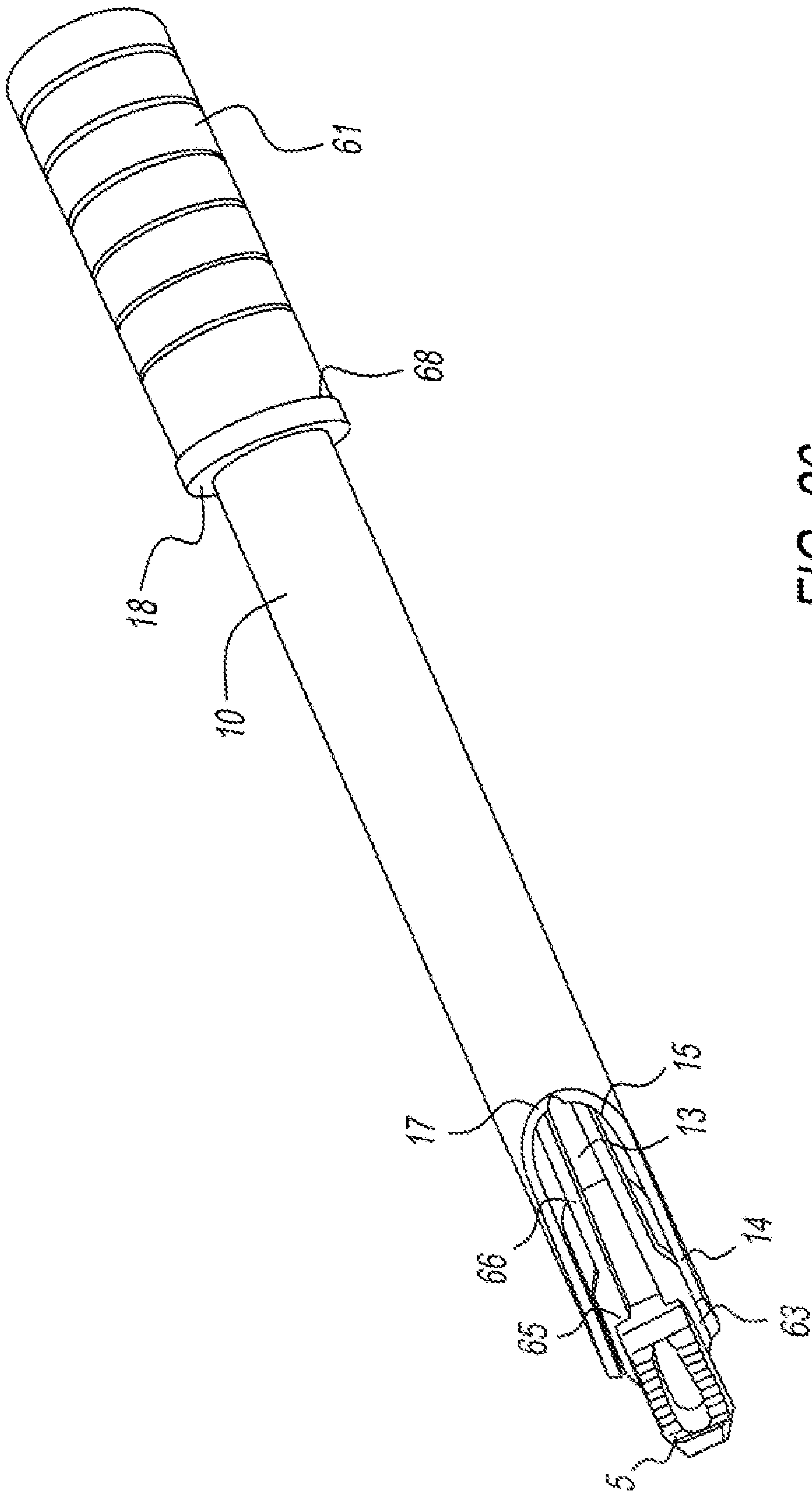


FIG. 26

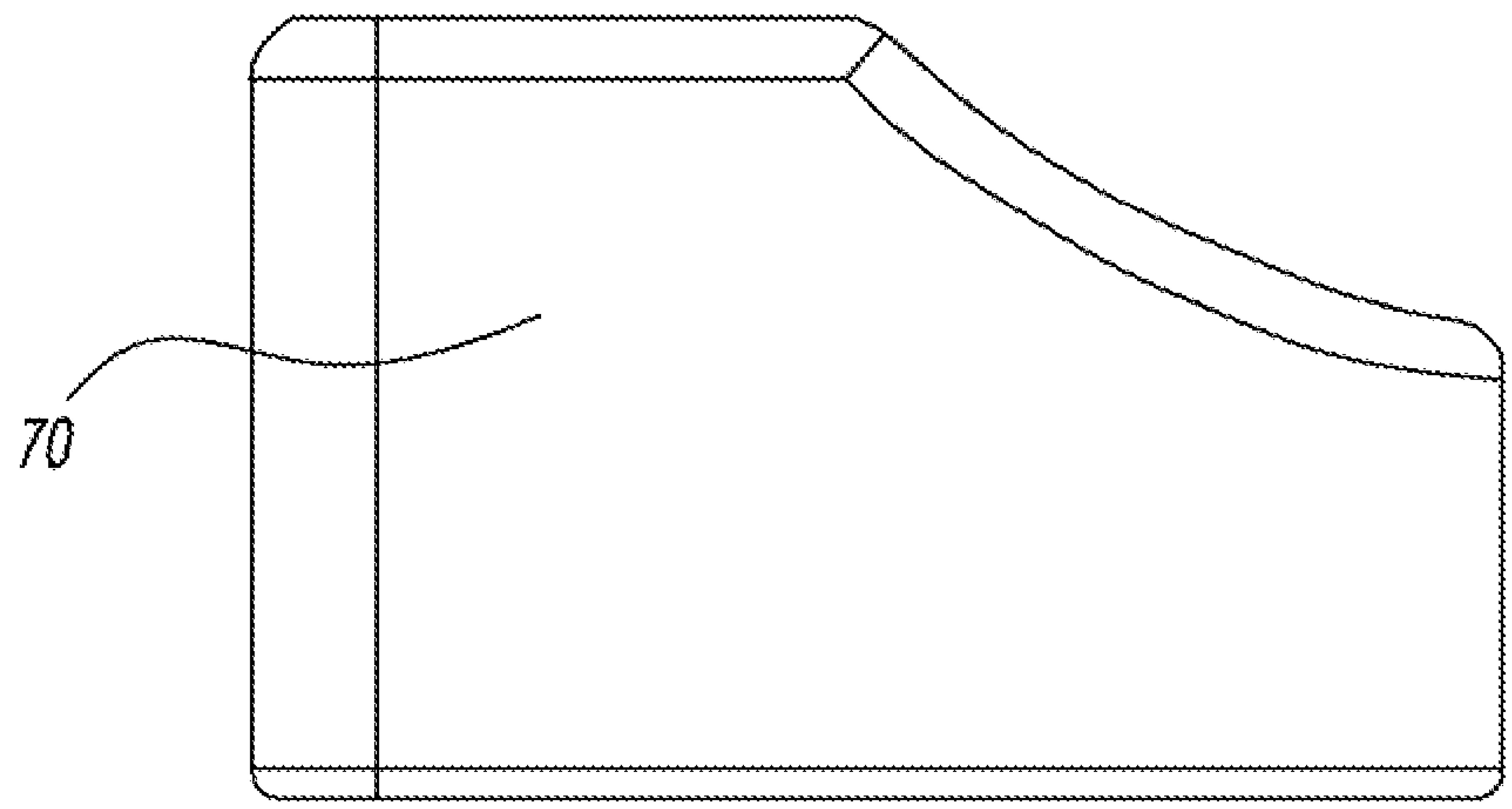


FIG. 27

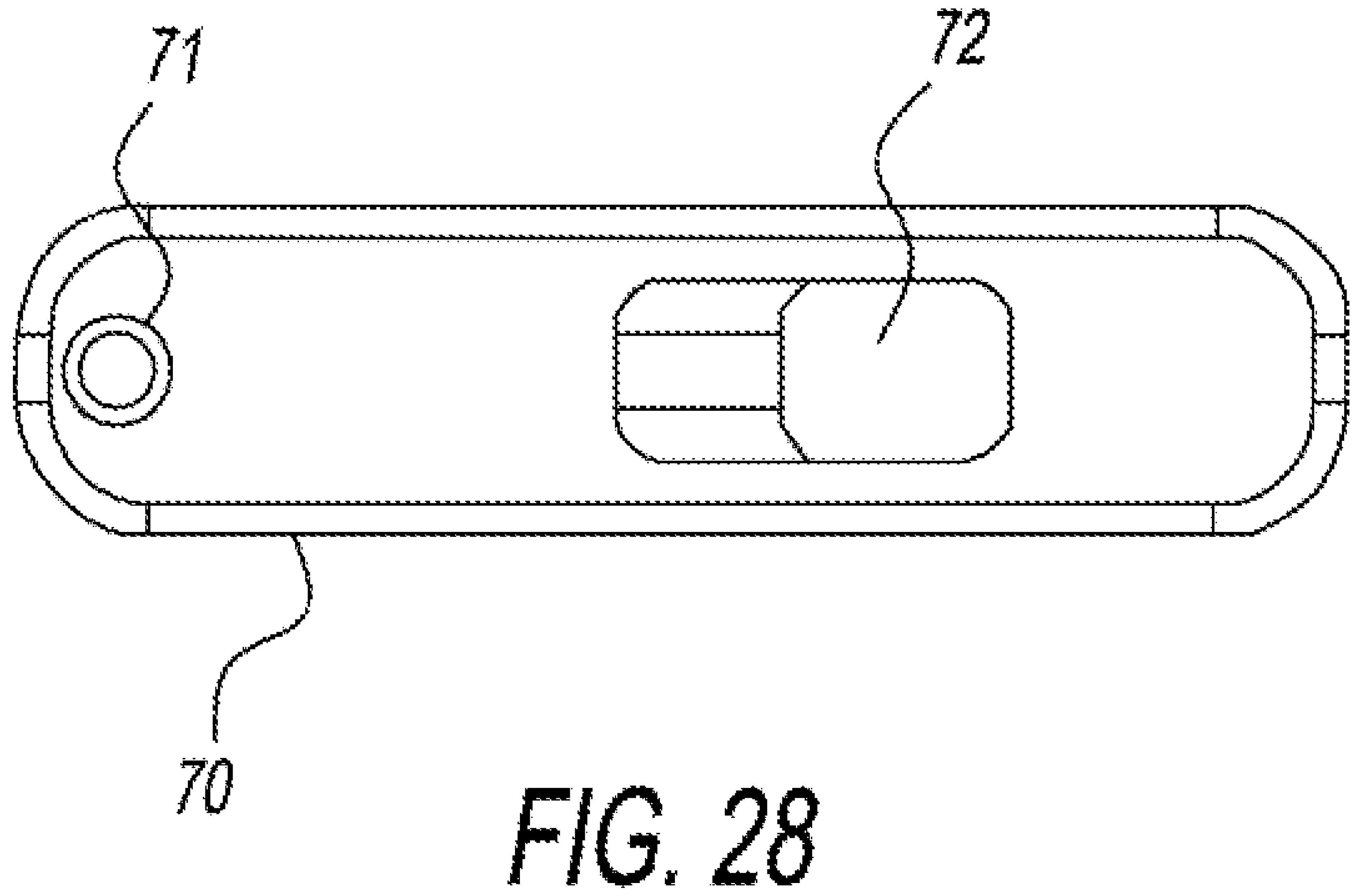


FIG. 28

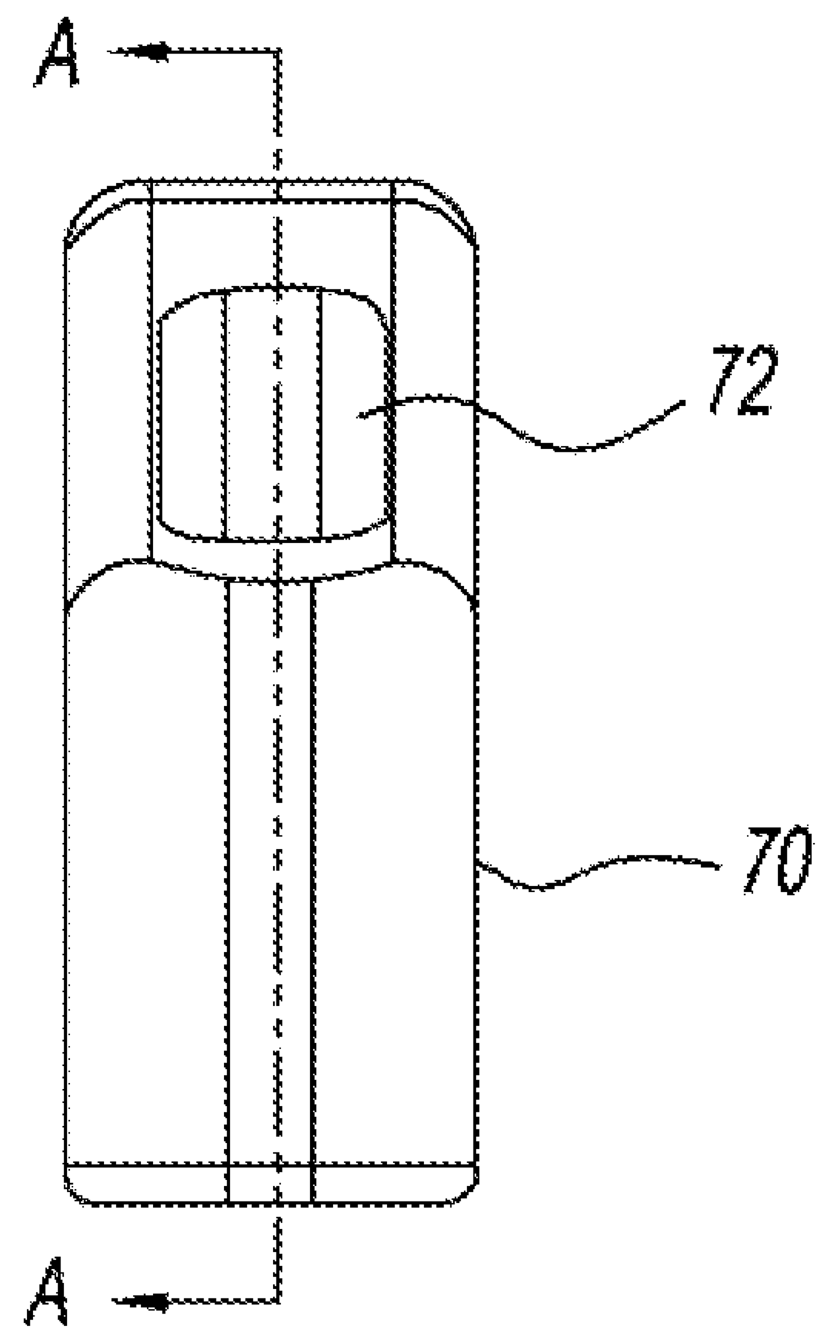


FIG. 29

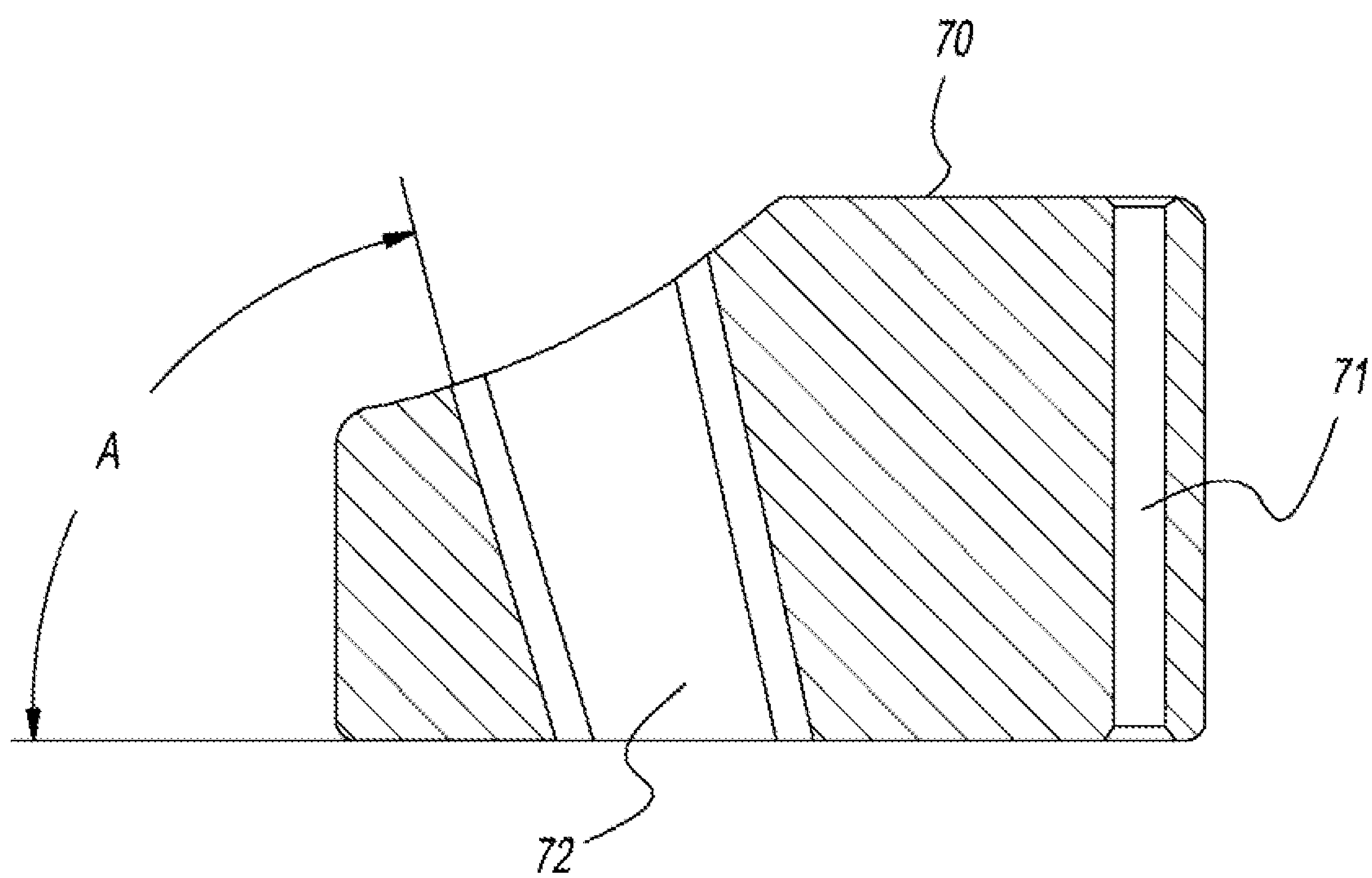


FIG. 30

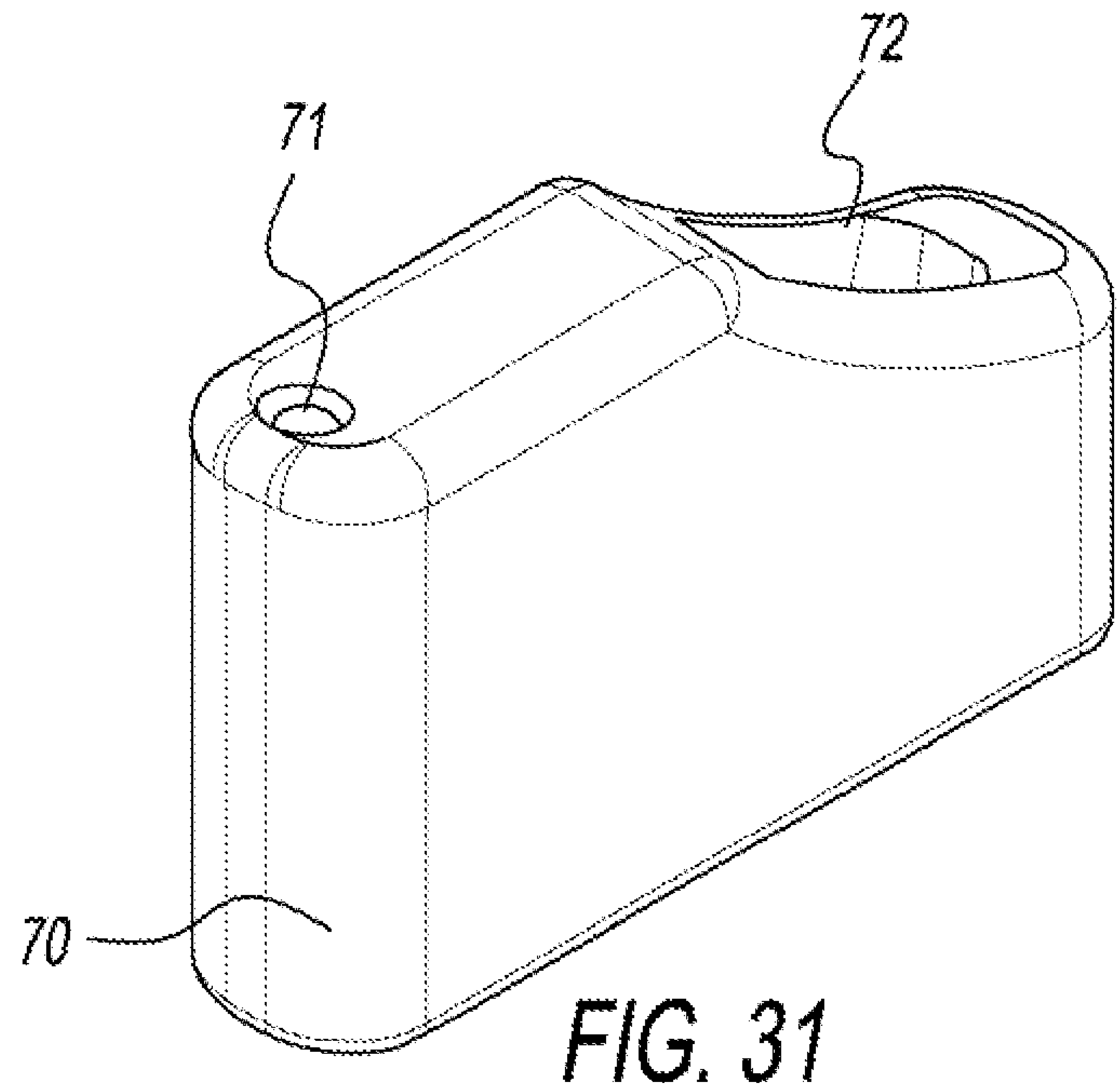


FIG. 31

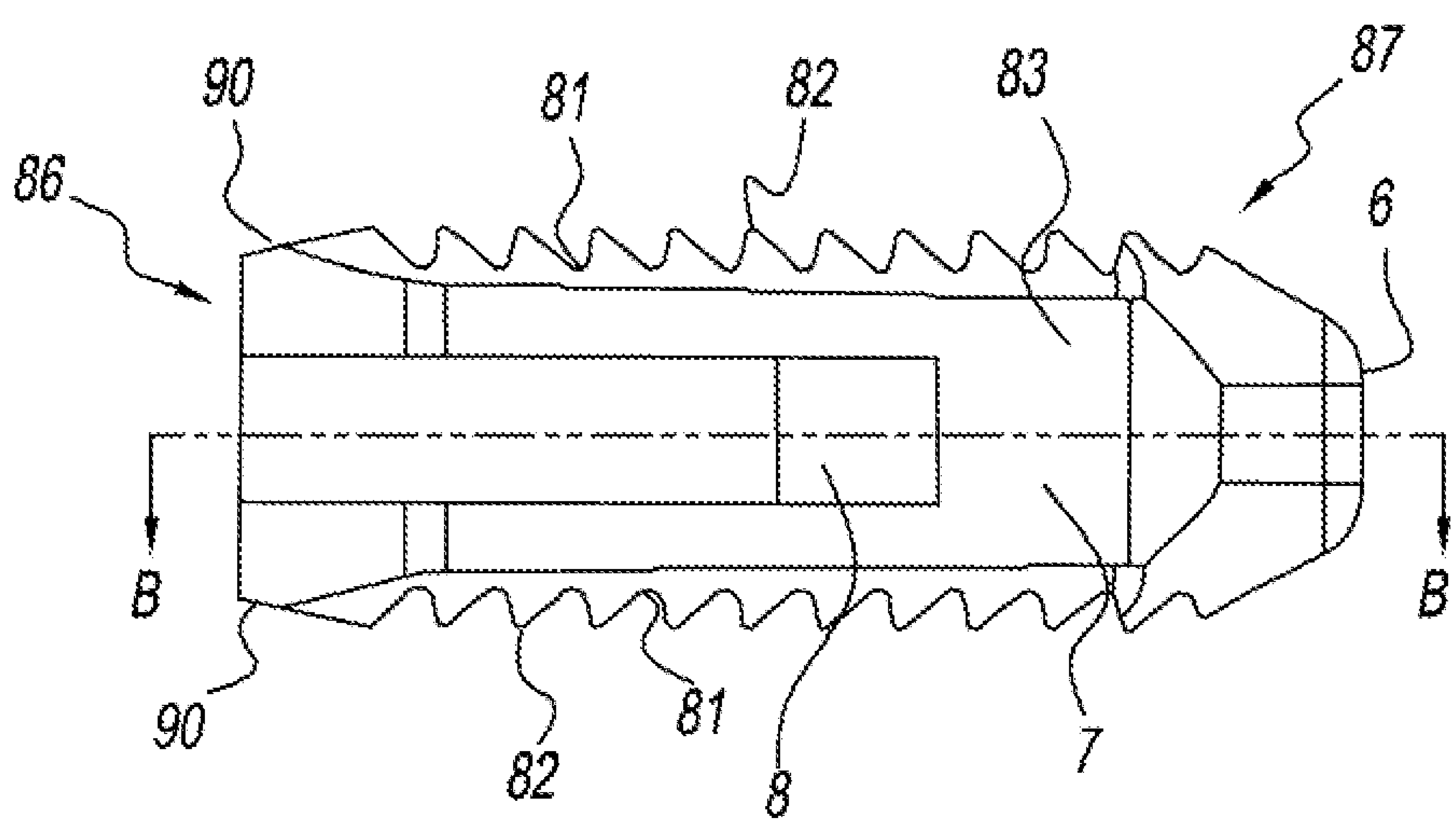


FIG. 32

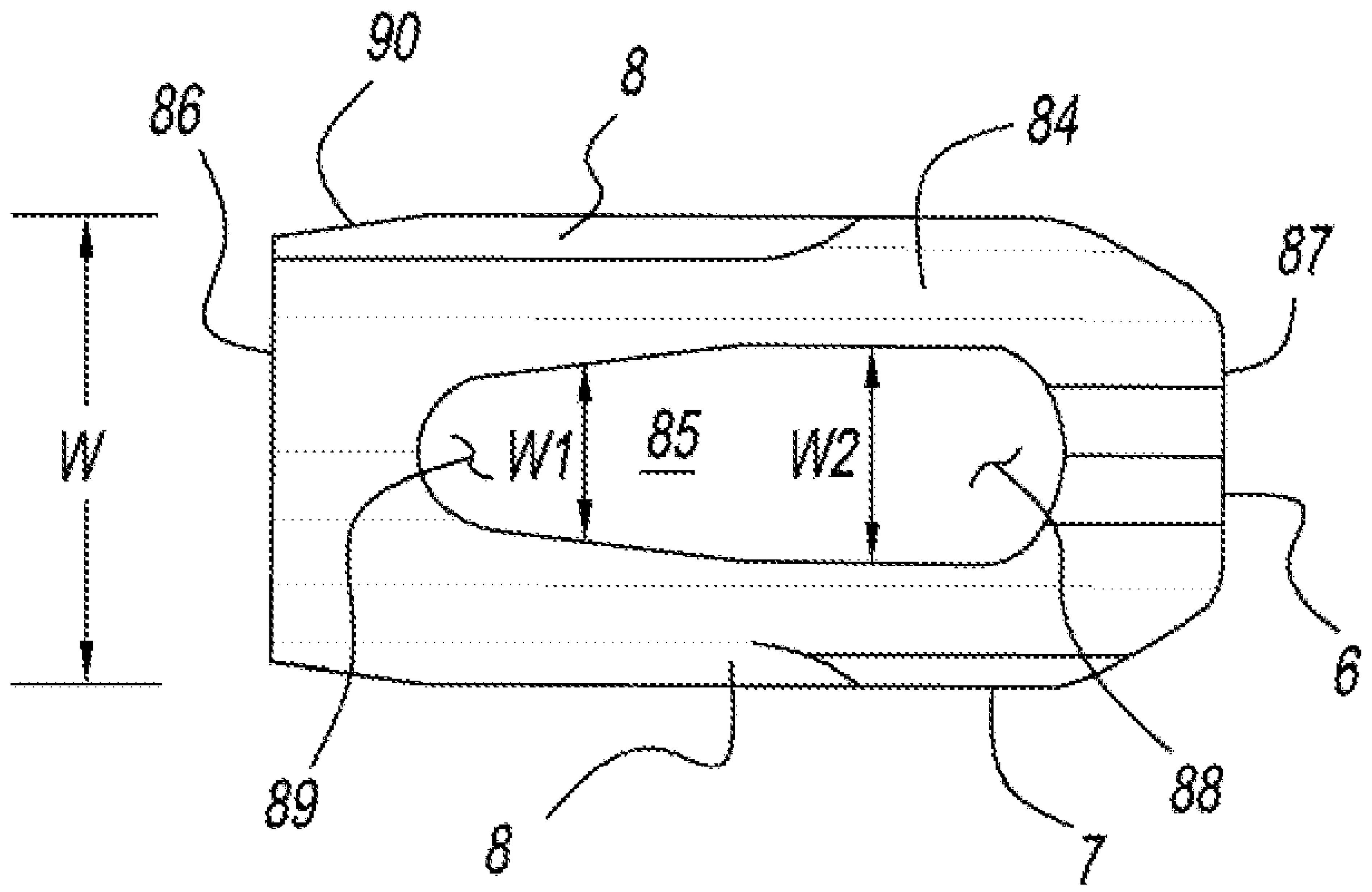


FIG. 33

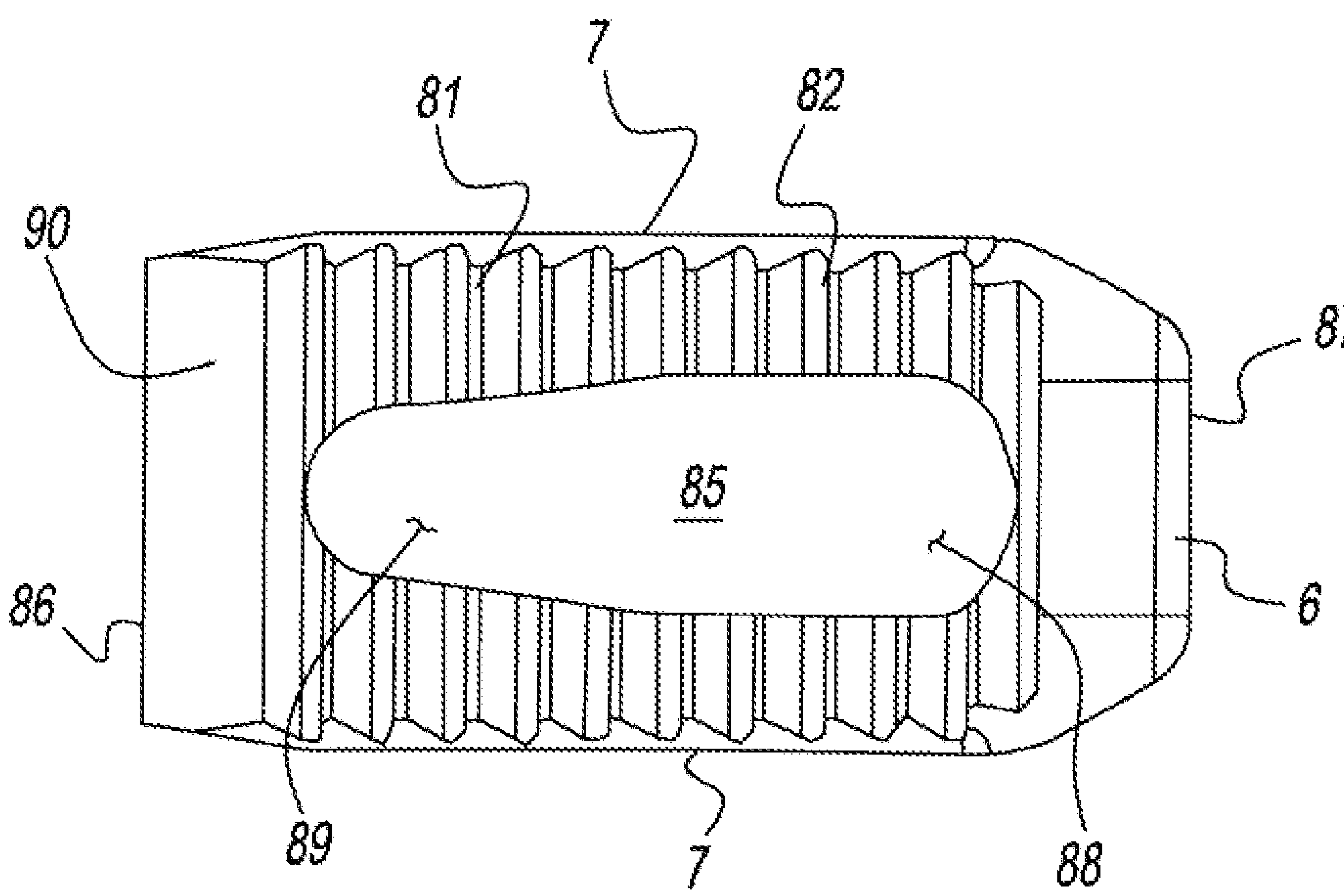
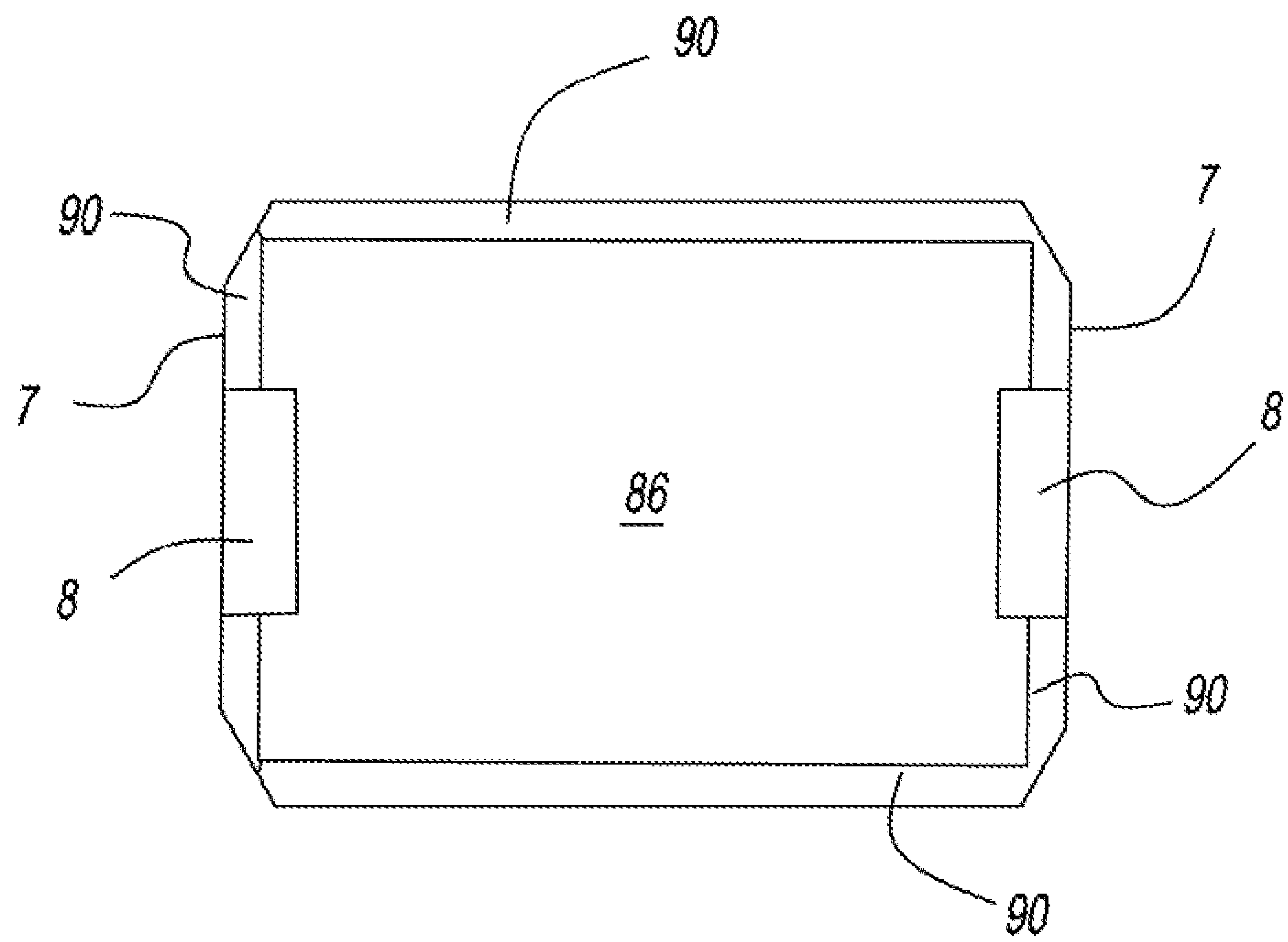


FIG. 34



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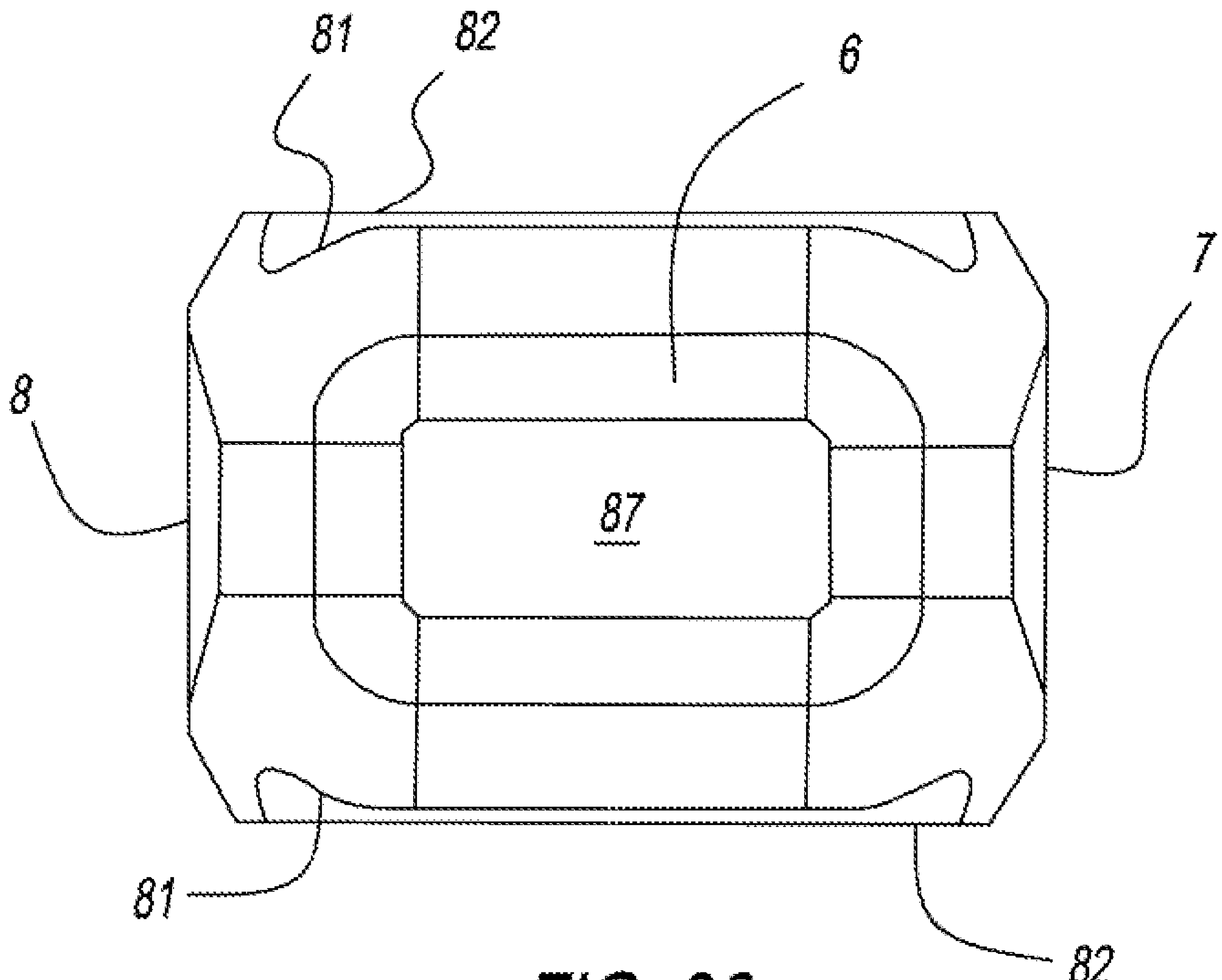

FIG. 36

METHOD OF FORMING AND DECORTICATING A VOID IN A SACROILIAC JOINT

CROSS-REFERENCE TO RELATED APPLICATIONS

Pursuant to 35 U.S.C. § 120, this application is a continuation of U.S. patent application Ser. No. 17/063,609, filed on Oct. 5, 2020, which is a continuation-in-part of U.S. patent application Ser. No. 16/851,840, filed on Apr. 17, 2020, which claims the benefit of U.S. Provisional Patent Application Ser. No. 62/910,913, filed on Oct. 4, 2019, the entire contents of each of which are incorporated herein by this reference.

BACKGROUND

(1) Field of Endeavor

The present invention relates generally to the field of sacroiliac joint fusion procedures, and more particularly, to a unique method of forming and decorticating an implant void for fusing a sacroiliac joint without the use of a rotary cutting instrument.

(2) Description of Related Art

The sacroiliac joint ("SI Joint") is located at the interface between the sacrum and ilium bones in a human's pelvic area. The SI Joint includes strong ligaments that permit only slight movement between the sacrum and the ilium. The sacrum is connected to the base of the spine, and each ilium is connected to the top of the leg and hip area. Thus, the SI Joint is the interface between a human's upper body and lower body.

Dysfunction in the SI Joint is a common problem of back pain. In fact, over 25% of back pain is caused by SI Joint dysfunction. Even a properly functioning SI Joint can become painful after certain types of spinal procedures. For example, over 75% of lumbar fusion surgeries lead to SI Joint pain. Often, SI Joint pain or dysfunction is addressed by fusing the SI Joint, and many past procedures exist for doing so. Past SI Joint fusion procedures involve installation of complex implant devices, such as bone anchors, fusion devices, and multi-component implants. These procedures involve complex devices, such as drills and drill bits, and multi-component dilators, braces, and anchor installation devices. As a result, fusion procedures using these devices are complex and time consuming, often leading to suboptimal results.

The present set of instruments seeks to overcome these problems by providing a streamlined system and procedure for installing an allograft implant in the SI Joint, without using a drill, drill bits, or other rotary cutting instruments.

Another complication of SI Joint fusion is that promoting bone fusion often involves decorticating the cortical bone inside the SI Joint. This decortication is accomplished with a broach, a rasp, or a similar abrading device. These abrading devices often become lodged inside the SI Joint during the decortication process. When the abrading device becomes lodged, counter pressure cannot be applied to the patient to counteract the pull-out force needed to dislodge the abrading device. Any such counter pressure applied to the patient could result in injury to the patient or damage to the tissue surrounding the surgical site. A past solution is to attach a separate slap hammer, or slide hammer, to the abrading device such that pull-out forces can be applied to the abrading device without the need for applying any counter pressure to the patient or to any other object. However, past slide hammer assemblies are cumbersome to operate, difficult to attach to the abrading device, and difficult to operate. They also complicate the instrumentation needed to perform the SI Joint fusion procedure.

The present set of instruments seeks to overcome these problems by providing a slide hammer integrated into the abrading device in a single tool, which eliminates the need for using a rotary cutting instrument in the bone of the SI Joint to form a pilot hole for the implant.

SUMMARY OF THE PREFERRED EMBODIMENTS

In one embodiment, the system and method described herein comprises a working channel, a joint locator, and an abrading device for forming an implant void in a sacroiliac joint. The working channel has an insertion end and a working end, and a channel extending therebetween. The working channel provides a working passage for insertion of the other instruments of the system, and for delivery of the implant to the SI Joint. The insertion end has a pair of arms for providing engagement of the SI Joint and distraction of tissue surrounding the insertion end. The insertion end further comprises a first iliac contour and a first sacral contour, both of which are defined by the contour between the insertion arms and the body of the working channel. The inside surface of the working channel has an alignment means comprising a groove, recess, channel, indent, or the like for receiving and engaging a ridge, rib, detent, or other protrusion on the mating instrument that is keyed to the alignment means. In one embodiment, the working channel further comprises a channel collar for receiving mating components of the joint locator, abrading device, or implant inserter in an abutting engagement.

The joint locator has an insertion end and a handle. The insertion end comprises a penetration tip for penetrating the soft tissue in proximity to the SI Joint. A leading edge of the penetration tip may comprise, in whole or in part, a blade or chisel component to promote this penetration. Alternately, the penetration tip may be rounded or dull so that it does not inadvertently penetrate the sacrum or ilium in the event that the joint locator is misaligned during insertion. The joint locator insertion end comprises a second iliac contour and a second sacral contour. The outside surface of the joint locator has a keying means for engagement with the alignment means of the working channel, the keying means comprising a ridge, rib, detent, or other protrusion on the outside surface of the joint locator capable of engaging the alignment means.

The abrading device comprises a hammer sleeve at a proximate end, an abrading head at a distal end, and a keying means that is similar to the joint locator keying means of the joint locator. In the preferred embodiment, the abrading device further comprises a slap hammer assembly, or slide hammer assembly. In one embodiment, the slide hammer assembly comprises a base connected to a shaft, and a releasing means that releasably connects a hammer sleeve to the base. The released hammer sleeve is configured for sliding engagement along the shaft. To operate the slide hammer assembly, the hammer sleeve is disengaged from the base, placing the slide hammer assembly in its released position. This released position enables the hammer sleeve to slide freely along the shaft. The hammer sleeve is pulled until a diaphragm inside the hammer sleeve engages a stop end of the shaft, thereby causing an impact that delivers the slide hammer force.

An implant inserter comprises a handle and an implant insertion end. The implant insertion end has a pair of tines for holding the implant during the process of inserting the implant into the SI Joint. The implant inserter further comprises an inserter keying means, which is similar to the keying means of the joint locator.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows the posterior view of a typical human pelvis.

FIG. **2** is a perspective view of an embodiment of an allograft implant for insertion into the SI Joint.

FIG. **3** shows an alternate view of one embodiment of an allograft implant.

FIG. **4** shows an embodiment of the instruments in the joint fusion apparatus.

FIG. **5** shows an embodiment of the working channel and an embodiment of the joint locator.

FIG. **6** shows a close up of the insertion end of one embodiment of a working channel.

FIG. **7** shows an alternate view of the embodiment shown in FIG. **6**.

FIG. **8** is an enlarged view of the insertion end of an embodiment of the joint locator fully inserted into the working channel of FIG. **4**.

FIG. **9** is an enlarged view showing the device of FIG. **8** with the orientation reversed.

FIG. **10** shows a close up of the working end of one embodiment of a working channel.

FIG. **11** shows the joint locator of FIG. **4** partially inserted into the working channel.

FIG. **12** shows the joint locator of FIG. **4** fully inserted into the working channel.

FIG. **13** shows the working channel of FIG. **4** and an embodiment of the abrading device.

FIG. **14** is an enlarged view of an embodiment of the abrading head.

FIG. **15** shows an enlarged view of one embodiment of an abrading head.

FIG. **16** shows the abrading device of FIG. **13** with an embodiment of a slide hammer disassembled.

FIG. **17** is an enlarged view of an embodiment of the connection interface of a slide hammer.

FIG. **18** shows a close up of one embodiment of the diaphragm and threaded connector of a slide hammer assembly.

FIG. **19** shows the abrading device of FIG. **13** partially inserted into the working channel of FIG. **4**.

FIG. **20** shows the abrading device of FIG. **13** fully inserted into the working channel of FIG. **4** with the slide hammer in its locked position.

FIG. **21** shows the abrading device of FIG. **13** fully inserted into the working channel of FIG. **4** with the slide hammer in its extended position.

FIG. **22** shows the working channel of FIG. **4** and an embodiment of the insertion device.

FIG. **23** is an enlarged view of the insertion end of the insertion device of FIG. **22**.

FIG. **24** shows the insertion device of FIG. **22** with an embodiment of an allograft implant loaded into the tines of the insertion end.

FIG. **25** shows the insertion device of FIG. **22** and the allograft implant partially inserted into the working channel of FIG. **4**.

FIG. **26** shows the insertion device of FIG. **22** and the allograft implant fully inserted into the working channel of FIG. **4**.

FIG. **27** is a front view of one embodiment of the incision guide.

FIG. **28** is a top view of one embodiment of the incision guide

FIG. **29** is a right side view of one embodiment of the incision guide.

FIG. **30** is a cross-sectional view A-A of the incision guide of FIG. **29**.

FIG. **31** is an isometric view of one embodiment of the incision guide.

FIG. **32** is a side view of one embodiment of an allograft implant.

FIG. **33** is a cross-sectional view B-B of the allograft implant of FIG. **32**.

FIG. **34** is a top view of one embodiment of an allograft implant.

FIG. **35** is a rear view of one embodiment of an allograft implant.

FIG. **36** is a front view of one embodiment of an allograft implant.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to the drawings, the method for fusing a sacroiliac joint ("SI Joint") now will be described with regard for the best mode and the preferred embodiment. The embodiments disclosed herein are meant for illustration and not limitation of the invention. An ordinary practitioner will appreciate that it is possible to create many variations of the following embodiments without undue experimentation.

The method and corresponding system and instrumentation described herein are used primarily for fusing an SI Joint **3** in the pelvis of a human. Referring to FIGS. **1-3**, an allograft implant **5** is placed in the soft tissue of the SI Joint **3** between the sacrum **1** and the ilium **2** of the pelvis. For the purpose of reference, the SI Joint plane as used herein means the general plane of the SI Joint **3** as defined by the abutting surfaces of the sacrum **1** and ilium **2**. The implant **5** provides a matrix for bone healing across the SI Joint, thereby fusing the sacrum **1** and ilium **2** together. In one embodiment, the implant **5** generally comprises a nose **6** and at least one pair of opposing lateral sides **7**, each comprising a groove **8** that is disposed at least partially along the length of each such lateral side **7**.

Referring to FIG. **4**, in one embodiment, the system comprises a working channel **10**, a joint locator **20**, an abrading device **30**, and an implant inserter **60**. Each of these instruments has a longitudinal axis along the centerline of its length. Referring to FIG. **5**, the working channel **10** is a tube-like member that provides a working passage for insertion of the other instruments of the system, and for delivery of the implant **5** to the SI Joint **3**. The working channel **10** is a cannula, a lumen, a sleeve, or another device suitable for providing working access of the other instruments to the SI Joint **3**, as described below. The working channel **10** has an insertion end **11** and a working end **12**, and a channel **13** extending therebetween. The channel **13** is a tube or bore having a cross section that is rectilinear or curvilinear. The insertion end **11** has a pair of arms **14** for providing engagement of the SI Joint **3** and distraction of tissue surrounding the insertion end **11**. The arms **14** are probes, prongs, or other members protruding from the insertion end **11** of the working channel **10**. Insertion of the arms **14** into the SI Joint **3**, as described below, resists or prevents the working channel **10** from rotating about its longitudinal axis in relation to the SI Joint **3**. The longitudinal axis generally extends along the length of the working channel **10** in proximity to the centerline of the channel **13**.

The insertion end **11** of the working channel **10** is configured for seating in and against the SI Joint **3**, and against the sacrum **1** and ilium **2** in particular. The insertion end **11** comprises a first iliac contour **15** and a first sacral contour **16**, both of which are defined by the contour between the insertion arms **14** and the body of the working channel **10**. For example, referring to FIGS. **6-9**, one side of the insertion end **11** comprises the arms **14** connected to the working channel **10** via the first iliac contour **15**, which is configured for abutment against the ilium **2** when the arms **14** are inserted into, and seated within, the SI Joint **3** as described below. The opposite side of the insertion end **11** comprises the arms **14** connected to the working channel **10** via the first sacral contour **16**, which is configured for abutment against the sacrum **1** when the arms **14** are inserted into, and seated within, the SI Joint **3**.

Referring to FIGS. **5** and **10**, the inside surface of the working channel **10** has a means for aligning instruments, the alignment means **17** comprising a groove, recess, channel, indent, or the like for receiving and engaging a ridge, rib, detent, or other protrusion on the mating instrument that is keyed to the alignment means **17**. In one embodiment, the working channel **10** further comprises a channel collar **18** for receiving mating components of the joint locator **20**, abrading device **30**, or implant inserter **60** in an abutting engagement, as described below. In an embodiment of the channel collar **18**, the collar further comprises an alignment means **17**.

Referring to FIG. **5**, the joint locator **20** has an insertion end **21** and a handle **22**, or working end. The insertion end **21** comprises a penetration tip **23** for penetrating the soft tissue in proximity to the SI Joint **3**. This soft tissue is the soft tissue between the surface of the patient's skin and the SI Joint **3**, such as muscle tissue, and the soft tissue inside the SI Joint **3**, such as cartilage and ligaments. The penetration tip **23** is configured for penetrating these types of soft tissue. For example, one embodiment of the penetration tip **23** comprises a blade or chisel component for cutting the soft tissue. A leading edge of the penetration tip **23** may comprise, in whole or in part, such a blade or chisel component. In another embodiment of the penetration tip **23**, the penetration tip **23** is rounded or dull so that it does not inadvertently penetrate the sacrum **1**, the ilium **2**, or any other bone structure in the pelvic area in the event that the joint locator **20** is misaligned during insertion and penetration. In this embodiment, the penetration tip **23** tends to tear or rip through the soft tissue rather than slicing or cutting through it.

Referring again to FIGS. **8** and **9**, the joint locator **20** insertion end **21** comprises a second iliac contour **24** and a second sacral contour **25**. For example, one side of the joint locator **20** insertion end **21** comprises the second iliac contour **24**, which is configured for abutment against the ilium **2** when the penetration tip **23** is inserted into the SI Joint **3**, as described below. The other side of the joint locator **20** insertion end **21** comprises the second sacral contour **25**, which is configured for abutment against the sacrum **1** when the penetration tip **23** is inserted into the SI Joint **3**.

The outside surface of the joint locator **20** has a means for keying with the alignment means **17** of the working channel **10**, the keying means **27** comprising a ridge, rib, detent, or other protrusion on the outside surface of the joint locator **20** capable of engaging the alignment means **17** to resist or prevent relative rotation between the joint locator **20** and the working channel **10**.

In one embodiment, referring to FIGS. **5**, **11**, and **12**, the joint locator **20** has a channel **26** for receiving the K-wire **4**. This channel **26** is a cannula, lumen, or other bore-like feature capable of receiving the K-wire **4** in a pass-through manner, preferably along a longitudinal axis, or centerline, of the joint locator **20**. In one embodiment of the joint locator **20**, the handle **22** further comprises a stop **28** for abutting against the channel collar **18** of the working channel **10**.

Referring to FIG. **13**, the abrading device **30** comprises a hammer sleeve **31** at a proximal end and an abrading head **32** at a distal end. The abrading head **32** is a rasp, broach, or other abrading tool that is used to grate, abrade, or otherwise decorticate the cortical bone inside the SI Joint **3**. In one embodiment, shown in FIGS. **14** and **15**, the abrading head **32** is a generally rectangular member comprising abrading surfaces **33** on a first pair of opposing sides **50** of the head **32**, an open tip **34** for insertion into the SI Joint **3**, and a second pair of opposing sides **35** between the abrading surfaces **33**, the second pair of opposing lateral sides **35** having one or more lateral openings. Each abrading surface **33** comprises one or more teeth, barbs, blades, ridges, slots, broaches, or other members or features capable of abrading the cortical bone in the SI Joint **3**. The open tip **34** comprises a cutting edge **36** around all or part of the leading edge of the open tip **34**, the cutting edge **36** configured for cutting bone tissue inside the SI Joint **3**, such as the sacrum **1** or ilium **2**. The abrading surfaces **33** and lateral sides **35** form a box-like abrading head **32** having a void therein. The openings in the lateral sides **35** enable lateral ingress into and egress from the void. For example, as the cutting edge **36** cuts bone tissue inside the SI Joint **3**, the dislodged bone tissue falls into the void and may exit the abrading head **32** via the openings in the lateral sides **35**.

In one embodiment, each side of the first pair of opposing sides **50** is a substantially planar member having a distal edge terminating at the open tip **34**, the interface between the open tip **34** and the distal edge comprising a substantially straight cutting edge **36**. Each side of the second pair of opposing sides **35** may comprise a curved distal portion terminating at the open tip **34**, the interface between the open tip **34** and the curved distal portion comprising a curved cutting edge **36**. The curved distal portion of each side of the second pair of opposing sides **35** may further comprise a taper toward its opposite side of the second pair of opposing sides **35**.

Referring to FIG. **19**, the abrading device **30** further comprises a keying means **37**, which is similar to the joint locator **20** keying means **27** described above. The keying means **37** mates with the alignment means **17** in the working channel **10** to resist or to prevent relative rotation between the abrading device **30** and the working channel **10** about each member's respective longitudinal axis. The abrading device **30** further comprises an abrading stop **38** for abutting against the channel collar **18** of the working channel **10**. In one embodiment, the abrading device **30** further comprises a K-wire channel for receiving the K-wire **4**. This K-wire channel is a cannula, lumen, or other bore-like feature capable of receiving the K-wire **4** in a pass-through manner, preferably along a longitudinal axis of the abrading device **30**.

Referring to FIGS. **16**, **17**, and **18**, the abrading device **30** further comprises a slap hammer assembly, or slide hammer assembly **40**. In one embodiment, the slide hammer assembly **40** comprises a base **51** connected to a shaft **44**, and a releasing means that releasably connects a hammer sleeve **31** to the base **51**. The released hammer sleeve **31** is configured for sliding engagement along the shaft **44**. The releasing means is any means for releasably connecting the hammer sleeve **31** to the base **51**, thereby transitioning the slide hammer assembly between its released position and its locked position. The releasing means could be a mating threaded connection, a quick disconnect attachment, a depressible tab, a latch, a clasp, a clip, a clamp, or other equivalent connection structure.

In one embodiment, shown in FIGS. **16**, **17**, and **18**, the releasing means is a mating threaded connection. This embodiment includes a collar **41** on the abrading device **30**, a slide hammer shaft **44**, and the hammer sleeve **31**. The collar **41** comprises internal threads **42** and external threads **43**. The shaft **44** comprises a threaded end **45** and a stop end **46**. The hammer sleeve **31** has a threaded connector **48** and a hollow, cylindrical bore comprising an internal diaphragm **47** having a diaphragm opening **49** (see FIG. **18**). The diaphragm opening **49** is sized to permit sliding passage of all parts of the shaft **44** except the stop end **46**. The stop end **46** is sized too large to fit through the diaphragm opening **49**.

To assemble the slide hammer assembly **40** of this embodiment, the threaded end **45** of the shaft **44** is inserted into the bore of the hammer sleeve **31**, through the diaphragm **47** inside the hammer sleeve **31**, and the threaded end **45** is threaded into, and mated with, the internal threads **42** of the collar **41**. The threaded connector **48** in the hammer sleeve **31** is then mated to the external threads **43** on the collar **41** to promote a secure connection. The stop end **46** is disposed inside the bore of the hammer sleeve **31** on a side of the diaphragm **47** opposite that of the location of the threaded connector **48**. In this configuration, shown in FIG. **20**, the slide hammer assembly **40** is in its locked position.

To operate the slide hammer assembly **40**, the threaded connector **48** is disengaged from the external threads **43** of the collar **41**, placing the slide hammer assembly **40** in its released position, which is shown in FIG. **21**. This released position enables the hammer sleeve **31** to slide freely along the shaft **44**. The hammer sleeve **31** is pulled until the diaphragm **47** inside the hammer sleeve **31** engages the stop end **46** of the shaft **44**, thereby causing an impact that delivers the slide hammer force. Thus, the slide hammer assembly has a released position that enables operation of the slide hammer assembly, and a locked position that prohibits operation of the slide hammer assembly.

Referring to FIGS. **22**-**26**, the implant inserter **60** comprises a handle **61** and an implant insertion end **62**. The implant insertion end **62** has a pair of tines **63** for holding the implant **5** during the process of inserting the implant **5** into the SI Joint **3**. Each tine **63** is supported by a tine shaft **66**, which terminates at a shoulder **67**. The tine shafts **66** provide flexibility such that the implant **5** is removably retained between the tines **63** with the shoulder **67** abutting against the implant **5** (see FIG. **24**). For example, in one embodiment the width of the implant **5** between the opposing grooves **8** is slightly larger than the space between the respective tines **63** such that when the implant **5** is seated in the implant insertion end **62**, the respective tines **63** are pushed slightly apart by the grooves **8**. This causes a slight amount of friction between the tines **63** and the grooves **8**, thereby releasably retaining the implant **5** in the implant insertion end **62**.

The implant inserter **60** further comprises an inserter keying means **65**, which is similar to the keying means **27** of the joint locator **20**. The inserter keying means **65** mates with the alignment means **17** in the working channel **10** to resist or to prevent relative rotation between the implant inserter **60** and the working channel **10** about each member's longitudinal axis. In one embodiment, the implant inserter **60** further comprises a channel **64** for receiving the K-wire **4** (see FIG. **23**). This channel **64** is a cannula, lumen, or other bore-like feature capable of receiving the K-wire **4** in a pass-through manner. In one embodiment of the implant inserter **60**, the handle **61** further comprises an inserter stop **68** for abutting against the channel collar **18** of the working channel **10**.

In one embodiment of a method of installing the implant **5**, the procedure for installing the implant **5** in the SI Joint **3** is started by locating an insertion point in the SI Joint **3**, which is the location where the implant **5** is to be installed. For example, the free end of the K-wire **4** is inserted into the SI Joint **3** at the insertion point where the implant **5** is to be installed, thereby defining an intended location for the implant void. The implant void is a seat or groove between the sacrum **1** and ilium **2** for seating the implant **5**, as described below. The K-wire **4** is preferably inserted from a posterior approach. It is preferable, but not required, that the implant **5** is installed under the portion of the posterior superior iliac spine that overhangs the SI Joint **3**. One or more alternate location are also suitable for fusion of the SI Joint **3**. A K-wire **4** is inserted into the SI Joint **3** at each location where an implant **5** is to be inserted.

In one embodiment, referring to FIGS. **27**-**31**, the initial incision is made using an incision guide **70** that comprises a channel **71** for removably receiving a K-wire **4**. The incision guide **70** further comprises a guide slot **72** for removably receiving a blade, scalpel, or similar cutting instrument (not shown). The guide slot **72** is disposed at an angle in relation to the channel **71** such that when the scalpel is extended through the guide slot **72**, the tip of the scalpel is disposed above the patient's skin at the proper location for making the initial incision into the patient. This location is above the SI Joint **3** where the allograft implant **5** will be introduced into the soft tissue above the SI Joint **3**, and eventually into the SI Joint **3** itself. In one embodiment, the guide slot **72** is oriented at an angle A of about 70° to about 75° in relation to horizontal H (see FIG. **30**). In this orientation, the channel **71** is perpendicular to horizontal.

In this embodiment, the K-wire **4** is inserted into the SI Joint **3** as described above. The incision guide **70** is placed over the K-wire **4** such that the K-wire **4** is slidably received into the channel **71**. In one embodiment, the scalpel is inserted into the guide slot **72** and retained in fixed relation to the channel **71** such that the cutting tip of the scalpel is located in close proximity to the K-wire **4**. The incision guide **70** is then advanced toward the SI Joint **3**, and the cutting tip of the scalpel makes the incision as the incision guide **70** advances. Once the initial incision is adequately formed, the incision guide **70** is lifted to remove it from the K-wire **4**, and the surgery proceeds with other instruments for inserting the implant **5** into the SI Joint **3**.

The joint locator **20** is then fully inserted into the working channel **10** (see FIG. **12**). In mating the joint locator **20** inside the working channel **10**, the keying means **27** of the joint locator **20** is oriented to engage the alignment means **17** of the working channel **10**. This engagement enables the first iliac contour **15** of the working channel **10** to be disposed in mating alignment with the second iliac contour **24** of the joint locator **20**, and the first sacral contour **16** of the working channel **10** to be disposed in mating alignment with the second sacral contour **25** of the joint locator **20** (see

FIGS. **8** and **9**). The respective first and second iliac contours **15**, **24** are configured to be seated in mating placement against the ilium **2** when the insertion end **11** is disposed inside the SI Joint **3**, and the respective first and second sacral contours **16**, **25** are configured to be seated in corresponding mating placement against the sacrum **1** when the insertion end **11** is disposed inside the SI Joint **3**. The stop **28** abuts against the channel collar **18** of the working channel **10** to prevent over penetration of the penetration tip **23** into the SI Joint **3**, thereby avoiding damage to the soft tissue and nerves on the anterior side of the SI Joint **3**.

The free end of the K-wire **4** is inserted into the K-wire channel **26** of the combined joint locator **20**/working channel **10**, and this combined device is advanced toward the SI Joint **3**, guided by the K-wire **4**. As the joint locator **20**/working channel **10** combination is advanced, the penetration tip **23** cuts or tears though the soft tissue above and inside the SI Joint **3**. If necessary, the combined joint locator **20**/working channel **10** is advanced via blows from a mallet against the proximal end of the handle **22** to deliver an appropriate axial force. The impact from the mallet causes an axial force that is transmitted though the handle **22** to the stop **28**, where the axial force is imparted to the channel collar **18** and into the working channel **10**. As such, the impact force from a mallet is shared between the working channel insertion end **11** and the joint locator insertion end **21**.

The combined joint locator **20**/working channel **10** is advanced until the respective first and second iliac contours **15**, **24** abut the ilium **2** and the respective first and second sacral contours **16**, **25** abut the sacrum **1**. In this position, the arms **14** of the working channel **10** are disposed inside the SI Joint **3** to retain the proper alignment of the working channel **10**, and therefore the alignment means **17**, thereby ensuring a proper alignment of the abrading device **30** and the implant inserter **60** later in the procedure. In some embodiments, insertion of the arms **14** into the SI joint **3** will distract the joint, thus separating the sacrum **1** and the ilium **2**. This distraction establishes a uniform width of the spacing in the SI joint **3** prior to use of the other instrumentation. Thus, the instrumentation described herein will work with a patient of any size because the arms **14** set the width of the SI joint **3** to a uniform distance regardless of the size or scale of the sacrum **1** or ilium **2**.

In an alternate embodiment of the installation method, a K-wire **4** is omitted from the procedure. Instead, the combined joint locator **20**/working channel **10** is advanced through an incision in the patient, and this advancement continues as described above until the insertion ends **11**, **21** are inserted into the SI Joint **3** as described above.

Once the combined joint locator **20**/working channel **10** device is properly seated in the SI Joint **3**, the joint locator **20** is removed from the working channel **10**. The surrounding soft tissue remains distracted or dilated by the working channel **10** and the respective arms **14**, thereby enabling direct access to the SI Joint **3** area. The abrading device **30** is then inserted into the working channel **10**, with the keying means **37** engaging the alignment means **17** to promote proper alignment of the abrading head **32** with respect to the SI Joint **3**. The abrading head **32** is advanced through the working channel **10** until the abrading head **32** makes contact with the SI Joint **3**. The abrading head **32** is forced into the SI Joint **3** (using a mallet if necessary), and the cutting edge **36** cuts the bone tissue and any soft tissue, such as ligaments or cartilage. The abrading stop **38** abuts against the channel collar **18** of the working channel **10** to prevent over penetration of the abrading head **32** into the SI Joint **3**, thereby avoiding damage to the soft tissue and nerves on the anterior side of the SI Joint **3**. During this process, the cutting edge **36** cuts through the relevant bone portions of the sacrum **1** and ilium **2**, and the abrading surfaces **33** work simultaneously in connection with the cutting edge **36** to decorticate the cortical bone inside the SI Joint **3**, thereby forming a decorticated implant void at the insertion point of the SI Joint **3**. The decorticated implant void has a generally rectangular cross sectional shape such that the decorticated implant void is adapted for receiving the fusion implant **5**, which has a generally rectangular cross sectional shape for mating with the decorticated implant void. Thus, use of the abrading head **32** enables installation of the implant **5** without the need for using a drill or other rotary cutting instrument to form a pilot hole for the implant **5**. As used herein, a rotary cutting instrument is any device capable of cutting material by turning, rotating, or other angular motion about an axis of the device, whether power-driven or hand-driven. This is a significant improvement of the present set of instruments over prior art methods and instrument sets for SI Joint **3** fusion.

The abrading device **30** is then worked in and out of the working channel **10** such that the abrading surfaces **33** abrade, or decorticate, the respective surfaces of the sacrum **1** and the ilium **2** inside the SI Joint **3**. Again, the abrading stop **38** abuts against the channel collar **18** to prevent over penetration of the abrading head **32**. During this process, the abrading head **32** may become lodged in the SI Joint **3**, becoming difficult to remove. In these instances, the slide hammer assembly **40** is enabled so that the abrading head **32** may be removed by the impact force of the slide hammer assembly **40**, as described above. Operation of the slide hammer assembly **40** provides a significant advantage over prior systems because when the abrading head **32** becomes lodged in the SI joint **3**, counter pressure cannot be applied to the patient to counter the pull-out force needed to dislodge the abrading head **32** from the SI joint **3**. The slide hammer assembly **40** enables removal of a lodged abrading head **32** in a safe manner without applying any counter pressure to the patient.

As the abrading head **32** is worked in and out of the SI Joint **3**, the abrading surfaces **33** abrade the cortical bone of the sacrum **1** and the ilium **2** inside the SI Joint **3**. The cortical bone is abraded until bleeding begins, thereby promoting the patient's healing process of the cortical bone. This degree of abrasion and corresponding healing promotes fusion of the SI Joint **3**.

Once the SI Joint **3** is adequately abraded, the abrading device **30** is removed from the working channel **10**. Thus, this method of fusing the SI Joint **3** comprises steps for forming a void for a fusion implant **5** in the SI Joint **3** without using a rotary cutting instrument. At this point in the procedure, the K-wire **4** may be removed from the working channel **10** to enable proper advancement of the implant **5** through the working channel **10** and proper installation of the implant **5** into the SI Joint **3**. Alternately, the K-wire **4** can be removed from the working channel **10** at any time after the working channel **10** is properly seated in the SI Joint **3**, as described above.

The allograft implant **5** is placed into the tines **63** of the implant inserter **60** such that each tine **63** is seated into a mating groove **8** on the lateral side **7** of the implant **5**, and the shoulder **67** abuts the implant **5** (see FIG. **24**). The implant inserter **60** is then inserted into the working channel **10** such that the keying means **65** engages the alignment means **17** to ensure proper orientation of the implant inserter **60**, and thus, the implant **5**. The implant inserter **60** is used to deliver the implant **5** to the abraded area of the SI Joint **3** through the working channel **10**. If necessary, the implant inserter **60** is struck by a mallet to force the implant **5** into the abraded area of the SI Joint **3**, the shoulder **67** transferring the impact force to the implant **5**. In these instances, the inserter stop **68** abuts against the channel collar **18** of the working channel **10** to prevent over penetration of the implant **5** into the SI Joint **3**, thereby ensuring that the implant **5** is properly placed inside the SI Joint **3**.

Once the implant **5** is fully inserted into the SI Joint **3**, the implant inserter **60** is removed from the working channel **10**, leaving the implant **5** installed in the abraded area of the SI Joint **3**. In most instances, the friction force between the implant **5** and the inside of the SI Joint **3** is greater than the friction force between the respective tines **63** and grooves **8**. In these instances, removal of the implant inserter **60** is accomplished by applying a removal force to the implant inserter **60** greater than the friction force between the tines **63** and the grooves **8**. The tines **63** slide out of the grooves **8** as the implant inserter **60** is retracted from the working channel **10**. In other instances, the friction force between the implant **5** and the inside of the SI Joint **3** is less than the friction force between the respective tines **63** and grooves **8**. In these instances, removal of the implant inserter **60** is accomplished by inserting a K-wire **4** or similar device into the K-wire channel **64** and advancing the K-wire **4** until the distal end of the K-wire **4** abuts against the implant **5** between the tines **63**. The K-wire **4** is used to hold the implant **5** in place inside the SI Joint **3** as the removal force is applied to the implant inserter **60**. The tines **63** are thereby removed from the grooves **8** as the K-wire **4** holds the implant **5** in its installed location. Once the tines **63** are pulled free from the grooves **8**, the implant inserter **60** is disengaged from the implant **5**, and the implant inserter **60** and the K-wire **4** are removed from the working channel **10**. The working channel **10** is then removed from the surgical site, causing the SI Joint **3** to contract, thereby exerting a compressive force on the implant **5**. This compressive force is caused by the ligaments of the SI Joint **3** that compress the joint, thereby holding it together. The surgical site is then sterilized and closed for healing.

As the abraded cortical bone heals, the bone fuses with the allograft implant **5**, eventually causing the sacrum **1** and the ilium **2** to grow together at the location of the implant **5**, thereby fusing the SI Joint **3**.

In any of the foregoing embodiments, one or more instruments may comprise disposable material, such as medical grade plastics, certain metals, or other disposable material.

Referring to FIGS. **32-36**, the implant **5** generally has two opposing faces **81**. When the implant **5** is inserted into the SI Joint **3**, one opposing face **81** is disposed against the sacrum **1**, and the other opposing face **81** is disposed against the ilium **2**. Each of the opposing faces **81** comprises one or more anti-migration features **82**, such as teeth or ridges, that resist movement of the implant inside the SI Joint **3**.

In one embodiment, the implant **5** comprises a body **83** having a proximal end **86**, a distal end **87**, and a length disposed therebetween, the distal end having a rounded nose **6**. The body **83** further comprises two sides **7**, each side **7** comprising a groove **8** beginning at the proximal end **86** of the body **83** and continuing along each of the two sides **7** for at least part of the length, the distance between the two sides **7** defining a width W of the body.

The implant **5** further comprises a central graft window **85** that enables fusion of the SI Joint **3** to occur through the implant **5**. The graft window **85** is disposed between each of the opposing faces **81**, the graft window **85** providing passage through the body **83** between the two opposing faces **81**. The portion of the body **83** located between the graft window **85** and each of the sides **7** defines a wall **84**.

When viewed in cross section (see FIG. **33**), the area of the graft window **85** is about 35% to about 40% of a first cross-sectional area of the body, which is the area of the total implant **5** as shown by the hatched area in FIG. **33**. The area of the window **85** is about 60% of the total area of each opposing face **81** that makes contact with the bone, whether the sacrum **1** or the ilium **2**. These ratios provide a strength-to-contact area relationship that optimizes performance of the implant **5** as a promoter of SI Joint **3** fusion. In these ratios, the implant **5** provides enough strength so that it is not crushed inside the SI Joint **3**, and it provides a large enough graft window **85** to expedite fusion of the SI Joint **3** across and through the implant **5**.

In one embodiment, the graft window **85** has a proximal portion **88** located in proximity to the grooves **8**, and a distal portion **89**, the proximal portion **88** having a width W1 that is less than a width W2 of the distal portion **89** such that the wall **84** maintains a minimum thickness in a range of about 17% to about 20% of the width W of the body **83**.

In the foregoing embodiments, it is preferable, but not required, that the graft window **85** is unobstructed by internal or intermediate supports. Such internal or intermediate supports are sometimes used in allograft implants to provide structural support to the implant. However, these internal or intermediate supports obstruct bone fusion from occurring through the window. As such, the graft window **85** may provide an open passage through the body **83** between the opposing faces **81**. The open passage may be rectilinear or curvilinear. The proximal end **86** of the body **83** may further comprise a taper **90** that reduces a second cross-sectional area of the body **83**.

The foregoing embodiments are merely representative of the SI Joint fusion method and not meant for limitation of the invention. For example, persons skilled in the art would readily appreciate that there are several embodiments and configurations of abrading devices, slide hammer devices, and other devices and instruments described herein that will not substantially alter the nature of the SI Joint fusion method. Some steps of the method can be performed in a sequence other than that described above. Consequently, it is understood that equivalents and substitutions for certain elements and components set forth above are part of the invention described herein, and the true scope of the invention is set forth in the claims below.

What is claimed is:

1. A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument, the method comprising the steps of:

locating an insertion point in the sacroiliac joint, the insertion point defining an intended location for the implant void;

introducing a working channel into the insertion point, the working channel having an insertion end and a working end, the insertion end of the working channel further comprising a first iliac contour, a first sacral contour, and insertion arms;

inserting the insertion arms into the sacroiliac joint at the insertion point such that the first sacral contour is seated against a sacrum bone and the first iliac contour is seated against an ilium;

introducing an abrading device into the working channel, the abrading device comprising:

an abrading head at a distal end of the abrading device, the abrading head having:

abrading surfaces on each of a first pair of opposing sides, the abrading surfaces capable of abrading a cortical bone of the sacroiliac joint; and

an open tip comprising a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint; and

advancing the abrading device into the sacroiliac joint such that the open tip cuts bone tissue away from the sacrum or the ilium and the abrading surfaces decorticate the cortical bone inside the sacroiliac joint, thereby forming a decorticated implant void at the insertion point without using a rotary cutting instrument.

2. The method of claim **1**, wherein introducing the working channel into the insertion point further comprises:

introducing a joint locator into the working channel, the joint locator having a penetration tip at an insertion end, the penetration tip comprising a second iliac contour and a second sacral contour; and

placing the first and second iliac contours and the first and second sacral contours in mating alignment by inserting the joint locator into the working channel, thereby defining a combined joint locator and working channel device.

3. The method of claim **2**, wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum and the first and second iliac contours are seated against the ilium.

4. The method of claim **3**, further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip until the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum.

5. The method of claim **1**, wherein forming the decorticated implant void at the insertion point further comprises forming a generally rectangular cross sectional shape for the decorticated implant void such that the decorticated implant void is adapted for receiving a fusion implant having a generally rectangular cross sectional shape.

6. The method of claim **5**, wherein introducing the working channel into the insertion point further comprises:

introducing a joint locator into the working channel, the joint locator having a penetration tip at an insertion end, the penetration tip comprising a second iliac contour and a second sacral contour; and

placing the first and second iliac contours and the first and second sacral contours in mating alignment by inserting the joint locator into the working channel, thereby defining a combined joint locator and working channel device.

7. The method of claim **6**, wherein inserting the insertion arms into the sacroiliac joint further comprises inserting the combined joint locator and working channel device into the sacroiliac joint at the insertion point such that the first and second sacral contours are seated against the sacrum and the first and second iliac contours are seated against the ilium.

8. The method of claim **7**, further comprising tearing through soft tissue above and inside the sacroiliac joint via the penetration tip until the first and second iliac contours abut the ilium and the first and second sacral contours abut the sacrum.

9. A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument, the method comprising the steps of:

locating an insertion point in the sacroiliac joint, the insertion point defining an intended location for the implant void;

introducing a working channel into the insertion point, the working channel having an insertion end and a working end, the insertion end further comprising insertion arms;

inserting the insertion arms into the sacroiliac joint at the insertion point;

introducing an abrading device into the working channel, the abrading device comprising:

an abrading head at a distal end of the abrading device, the abrading head having:

abrading surfaces on each of a first pair of opposing sides, the abrading surfaces capable of abrading a cortical bone of the sacroiliac joint; and

an open tip comprising a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint; and

advancing the abrading device into the sacroiliac joint such that the open tip cuts bone tissue away from a sacrum or an ilium; and

decorticating the cortical bone inside the sacroiliac joint using the abrading surfaces;

thereby forming a decorticated implant void at the insertion point without using a rotary cutting instrument.

10. The method of claim **9**, wherein forming the decorticated implant void at the insertion point further comprises forming a generally rectangular cross sectional shape for the decorticated implant void such that the decorticated implant void is adapted for receiving a fusion implant having a generally rectangular cross sectional shape.

11. A method of forming an implant void in a sacroiliac joint without the use of a rotary cutting instrument, the method comprising the steps of:

making an incision in a patient's skin via an incision guide that comprises:

a channel for removably receiving a K-wire; and

a guide slot for removably receiving a cutting instrument, the guide slot disposed at an angle in relation to the channel;

locating an insertion point in the sacroiliac joint, the insertion point defining an intended location for the implant void;

introducing a working channel through the incision and into the insertion point, the working channel having an insertion end and a working end, the insertion end further comprising insertion arms;

aligning the working channel in a plane substantially parallel to a plane defined by the articular surfaces of the sacroiliac joint by inserting the insertion arms into the sacroiliac joint at the insertion point;

introducing an abrading device into the working channel, the abrading device comprising:

an abrading head at a distal end of the abrading device, the abrading head having:

abrading surfaces on each of a first pair of opposing sides, the abrading surfaces capable of abrading a cortical bone of the sacroiliac joint; and

an open tip comprising a cutting edge disposed at a leading edge of the open tip, the cutting edge configured to cut bone tissue in the sacroiliac joint; and

advancing the abrading device into the sacroiliac joint such that the open tip cuts bone tissue away from a sacrum or an ilium; and decorticating the cortical bone inside the sacroiliac joint using the abrading surfaces;

thereby forming a decorticated implant void at the insertion point without using a rotary cutting instrument.

12. The method of claim **11**, wherein forming the decorticated implant void at the insertion point further comprises forming a generally rectangular cross sectional shape for the decorticated implant void such that the decorticated implant void is adapted for receiving a fusion implant having a generally rectangular cross sectional shape.

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